SHOOK, HARDY & BACON L.L.P.
Brian M. Lands, Esq. (NJ Bar #107272014)
Two Commerce Square
2001 Market Street, Suite 3000
Philadelphia, PA 19103
Telephone: 215.278.2555
blands@shb.com
Attorney for Defendant
Regeneron Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WILLIAM DOUGLAS, Plaintiff, v. REGENERON PHARMACEUTICALS, INC.; and SANOFI-AVENTIS U.S. LLC, Defendants.	Civil Action No. _____

DEFENDANT REGENERON PHARMACEUTICALS, INC.'S NOTICE OF REMOVAL

Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Defendant"), by and through undersigned counsel, hereby gives notice of removal of this action pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, from the Superior Court of New Jersey, Law Division, Atlantic County (the "State Court Action"), to the United States District Court for the District of New Jersey. In support of this Notice of Removal, Regeneron states as follows:

REMOVAL STANDARD

1. Pursuant to 28 U.S.C. § 1441(a), "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant . . . to the district court of the United States for the district and division embracing the place where such action is pending."

2. Under 28 U.S.C. § 1332(a), federal courts have original jurisdiction over any civil action "where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between . . . citizens of different States[.]"

3. To remove a case from a State court to federal court, a defendant must file in the federal forum a notice of removal "containing a short and plain statement of the grounds for removal." 28 U.S.C. § 1446(a). "[T]he notice of removal may assert the amount in controversy if the initial pleading seeks . . . a money judgment, but the State practice either does not permit demand for a specific sum or permits recovery of damages in excess of the amount demanded," and, "if the district court finds, by the preponderance of the evidence, that the amount in controversy exceeds the amount specified in section 1332(a)." 28 U.S.C. § 1446(c)(2)(A) & (B). "A statement 'short and plain' need not contain evidentiary submissions." *Dart Cherokee Basin Operating Co., LLC v. Owens*, 574 U.S. 81, 83 (2014).

THE REMOVED CASE

4. The removed State Court Action is a product liability action arising out of Plaintiff's diagnosis with mycosis fungoides, a form of cutaneous T-cell lymphoma ("CTCL"), which Plaintiff alleges was caused by his use of Dupixent. (*See* Ex. A, Compl. ¶¶ 1–4, 27–28).

5. Plaintiff brings claims for: (I) strict liability – failure to warn; (II) strict liability – design defect; (III) negligence; (IV) negligent misrepresentation; (V) breach of express warranty; (VI) breach of implied warranty; (VII) violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.; and (VIII) punitive damages. (*See* Ex. A, Compl. Counts I–VIII).

PAPERS FROM THE REMOVED CASE

6. Pursuant to 28 U.S.C. § 1446(a), Regeneron attaches to this Notice of Removal a copy of all process, pleadings, and other papers or exhibits of every kind, including depositions, on file in the state court. *See* Ex. A.

THE REMOVAL IS TIMELY

7. Under 28 U.S.C. § 1446(b), a defendant must file its notice of removal "within 30 days after the receipt by the defendant, through service or otherwise, of a copy of the initial pleading setting forth the claim for relief upon which such action or proceeding is based." 28 U.S.C. § 1446(b)(1).

8. Plaintiff filed this action in state court on June 11, 2026.

9. Plaintiff served Regeneron on June 11, 2026. Plaintiff has not yet served Sanofi.

10. This Notice of Removal is timely under 28 U.S.C. § 1446(b) because the 30-day period to remove under § 1446(b)(1)—which runs from a defendant's receipt of the initial pleading "through service or otherwise"—has not yet expired.

VENUE IS PROPER

11. Without waiving Regeneron's right to challenge, among other things, personal jurisdiction by way of motion, responsive pleadings, or otherwise, venue for this removed action lies in the District of New Jersey pursuant to 28 U.S.C. § 1391 because the Atlantic County Superior Court, where the Complaint was filed, is a state court within the District of New Jersey. *See* 28 U.S.C. § 1441(a).

REMOVAL IS PROPER UNDER DIVERSITY JURISDICTION

I. COMPLETE DIVERSITY OF CITIZENSHIP EXISTS BETWEEN THE PARTIES.

A. Complete Diversity of Citizenship Exists

12. This civil action falls under the Court's original jurisdiction under 28 U.S.C. § 1332 (diversity of citizenship) and may be removed to this Court based on diversity of citizenship pursuant to 28 U.S.C. §§ 1441 and 1446.

13. A natural person is deemed to be a citizen of the state where he is domiciled. *Swiger v. Allegheny Energy, Inc., 540 F.3d 179, 182* (3d Cir. 2008) (*citing Gilbert v. David*, 235 U.S. 561, 569 (1915)).

14. Plaintiff is domiciled in Memphis, Tennessee and is therefore a citizen of Tennessee. (*See* Ex. A, Compl. ¶¶ 5, 20).

15. A corporation shall be deemed to be a citizen of the state in which it is incorporated and the state of its principal place of business. 28 U.S.C. § 1332(c)(1).

16. Regeneron is a New York corporation with its principal place of business in New York. As such, Regeneron is a citizen of New York.

17. Sanofi-Aventis U.S. LLC is a limited liability company organized under the laws of Delaware with its principal place of business in Bridgewater, New Jersey. (*See* Ex. A, Compl. ¶ 6). For purposes of diversity jurisdiction, the citizenship of a limited liability company is determined by the citizenship of each of its members. *See Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 420 (3d Cir. 2010). Sanofi-Aventis U.S. LLC's sole member is Sanofi US Services, Inc., a corporation incorporated in Delaware that, upon information and belief, maintains its principal place of business in New Jersey. As such, Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey.

18. Complete diversity exists because Plaintiff, on the one hand, and Defendants, on the other, "are citizens of different States." *See* 28 U.S.C. § 1332(a). No Defendant is a citizen of Tennessee.

B. No Forum Defendant Has Been Properly Served

19. The "forum defendant rule" provides that "[a] civil action otherwise removable solely on the basis of [diversity] may not be removed if any of the parties in interest properly joined *and served* as defendants is a citizen of the State in which such action is brought." 28 U.S.C. § 1441(b)(2) (emphasis added).

20. Regeneron is not, and was not at the time of filing, a citizen of the State of New Jersey within the meaning of the Acts of Congress relating to the removal of actions. 28 U.S.C. § 1332(c)(1).

21. The only other Defendant is Sanofi-Aventis U.S. LLC. Because Sanofi-Aventis U.S. LLC has not been served in this case, its citizenship is not an impediment to removal under 28 U.S.C. § 1441(b).

22. Pursuant to 28 U.S.C. § 1441(b), this action is removable because no party in interest properly joined *and served* as a defendant is a citizen of the State of New Jersey, the state in which this action was brought. The forum defendant rule "precludes removal on the basis of in-state citizenship only when the defendant has been properly joined and served," and thus does not bar a non-forum defendant such as Regeneron from removing a diversity action before any forum defendant has been served. *See Encompass Ins. Co. v. Stone Mansion Rest., Inc.*, 902 F.3d 147, 152 (3d Cir. 2018).

II. THE AMOUNT IN CONTROVERSY EXCEEDS $75,000.

23. For a case to be removed under 28 U.S.C. § 1332(a), the amount in controversy in an action must "exceed[] the sum or value of $75,000." Defendant denies that Plaintiff is entitled to any relief and does not waive any defenses to any of Plaintiff's claims, but under 28 U.S.C. §

1446(c)(2)(B), removal is proper if the court finds, by a preponderance of the evidence, that the amount in controversy exceeds $75,000, exclusive of interest and costs.

24. "The amount in controversy is not measured by the low end of an open-ended claim, but rather by a reasonable reading of the value of the rights being litigated." *Auto-Owners Ins. Co. v. Stevens & Ricci*, 835 F.3d 388, 401 (3d Cir. 2016) (*quoting Angus v. Shirley*, 989 F.2d 142, 146 (3d Cir. 1993)).

25. Here, Plaintiff alleges that he developed mycosis fungoides, a rare form of cutaneous T-cell lymphoma, as a result of his use of Dupixent. (*See* Ex. A, Compl. ¶¶ 27–28).

26. As a result of his alleged injuries, Plaintiff claims to have suffered serious and permanent bodily injuries, past and future medical and nursing expenses, pain and suffering, disability, mental anguish, loss of the capacity for the enjoyment of life, and aggravation of previously existing conditions. (*See* Ex. A, Compl. ¶¶ 28, 317, 360). Plaintiff further seeks general and special damages, exemplary and punitive damages, and treble damages under the New Jersey Consumer Fraud Act. (*See* Ex. A, Compl., Prayer for Relief ¶¶ a–d).

27. Allegations analogous to these have been held by federal courts in this District to establish that the amount in controversy exceeds the jurisdictional requirement. *See, e.g.*, *Briggs v. Target Corp.*, No. 14-7165-RBK-JS, 2015 U.S. Dist. LEXIS 30796, at *9 (D.N.J. Mar. 13, 2015) ("the District of New Jersey has found that allegations of serious injuries in addition to pain and suffering indicate that the amount in controversy exceeds $75,000"); *see also Small v. Braxton*, No. 22-513-JXN-MAH, 2022 U.S. Dist. LEXIS, at *13–14 (D.N.J. Dec. 7, 2022) (holding that amount in controversy exceeded $75,000 where plaintiff's alleged "severe injuries, pain, past and future medical expenses, and deprivation of the ability to engage in their usual activities, including work…"); *Clark v. J.C. Penney Corp.*, No. 08-CV-4083, 2009 U.S. Dist. LEXIS 129380, at *3–4

(D.N.J. June 1, 2009) (plaintiff's claims for "'serious, painful and permanent bodily injuries,' 'great physical pain and mental anguish,' and 'substantial medical expenses'" exceeded the jurisdictional threshold); *McCall v. New Prime, Inc.*, No. 12-02442-JAP, 2012 U.S. Dist. LEXIS 124473, at *3 (D.N.J. Aug. 31, 2012) (holding that amount in controversy requirement is satisfied where "plaintiff…alleges severe and permanent injuries, including future medical expenses and loss of earnings, and has refused to stipulate to damages below 75,000.").

28. Plaintiff also seeks attorneys' fees, costs of suit, and pre- and post-judgment interest. (*See* Ex. A, Compl., Prayer for Relief ¶¶ d–f). "[A]n award of attorneys' fees must be included as part of the amount in controversy determination where such an award is provided for by statute." *Smith v. HSN, Inc.*, No. 20-12869-JSN-ESK, 2022 U.S. Dist. LEXIS 148893, at *7 (D.N.J. Aug. 18, 2022); *see also Suber v. Chrysler Corp.*, 104 F.3d 578, 585 (3d Cir. 1997) ("in calculating the amount in controversy, we must consider potential attorney's fees.").

29. Accordingly, the amount in controversy clearly exceeds $75,000.

30. The State Court Action may be removed to this Court by Defendant in accordance with the provisions of 28 U.S.C. § 1441(a) because (i) this action is a civil action pending within the jurisdiction of the United States District Court for the District of New Jersey; (ii) this action is between citizens of different states; and (iii) the amount in controversy exceeds $75,000, exclusive of interest and costs.

CONSENT TO REMOVAL

31. Pursuant to 28 U.S.C. § 1446(b)(2)(A), "all defendants who have been properly joined and served must join in or consent to the removal of the action."

32. Because Sanofi-Aventis U.S. LLC has not been properly joined *and served*, the requirements of 28 U.S.C. § 1446(b)(2)(A) are satisfied.

FILING OF REMOVAL PAPERS

33. Pursuant to 28 U.S.C. § 1446(d), written notice of the removal of this action will be promptly served to Plaintiff's counsel.

34. Pursuant to 28 U.S.C. § 1446(d), Defendant will file a Notice to Court of Filing of Removal, including a true and correct copy of this Notice of Removal, with the Clerk of the Superior Court of New Jersey, Law Division, Atlantic County.

35. The allegations in this Notice are true and correct and within the jurisdiction of the United States District Court for the District of New Jersey, and this case is removable to the United States District Court for the District of New Jersey.

36. If any question arises as to the propriety of removal here, Regeneron requests the opportunity to present a brief and oral argument supporting its position that this case is removable.

37. Defendant requests a trial by jury of all issues.

WHEREFORE, Defendant Regeneron removes the matter entitled *William Douglas v. Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc., originally filed in the Superior Court of New Jersey, Law Division, Atlantic County, Case No. ATL-L-001199-26*, to the United States District Court for the District of New Jersey, and requests that further proceedings be conducted in this Court.

Dated: June 11, 2026

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By: */s/ Brian M. Lands*

Brian M. Lands, Esquire
Two Commerce Square
2001 Market Street, Suite 3000
Philadelphia, PA 19103
Telephone: 215.278.2555
blands@shb.com
Attorney for Defendant
Regeneron Pharmaceuticals, Inc.

SHOOK, HARDY & BACON L.L.P.
Brian M. Lands, Esq. (NJ Bar #107272014)
Two Commerce Square
2001 Market Street, Suite 3000
Philadelphia, PA 19103
Telephone: 215.278.2555
blands@shb.com
Attorneys for Defendant
Regeneron Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WILLIAM DOUGLAS, Plaintiff, v. REGENERON PHARMACEUTICALS, INC.; and SANOFI-AVENTIS U.S. LLC, Defendants.	Civil Action No. _____

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendant Regeneron Pharmaceuticals, Inc. states upon information and belief that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 11, 2026

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By: */s/ Brian M. Lands*
Brian M. Lands, Esquire
Two Commerce Square
2001 Market Street, Suite 3000
Philadelphia, PA 19103
Telephone: 215.278.2555
blands@shb.com
Attorney for Defendant
Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on June 11, 2026, a true and correct copy of the foregoing NOTICE OF REMOVAL was filed electronically and notice of the filing of this document will be sent to the following known counsel and parties of record in the underlying State Court Action:

Ellen Relkin
Laura J. Baughman
WEITZ & LUXENBERG, P.C.
220 Lake Drive East, Suite 210
Cherry Hill, New Jersey 08002
Phone: 856-755-1115
erelkin@weitzlux.com

Attorneys for Plaintiff

/s/ Brian M. Lands
Brian M. Lands, Esquire

Attorney for Defendant
Regeneron Pharmaceuticals, Inc.

EXHIBIT A

Civil Part Case Summary

Case Number: ATL L-001199-26

Case Caption: Douglas William Vs Sanofi-Aventis U.S. Llc

Court: Civil Part
Venue: Atlantic
Case Initiation Date: 06/11/2026
Case Type: Product Liability
Case Status: Active
Jury Demand: 6 Jurors
Case Track: 3
Judge: Sarah B Johnson
Team: 102
Original DED:
Current DED:
# of DED Extensions: 0
Original Arb Date:
Current Arb Date:
# of Arb Adjournments: 0
Original Trial Date:
Current Trial Date:
# of Trial Adjournments: 0
Disposition Date:
Case Disposition: Open
Statewide Lien:

Plaintiffs

William Douglas

Party Description: Individual
Phone:
Address Line 1:
Address Line 2:
City:
State: NJ
Zip: 00000
Attorney Name: Relkin Ellen
Attorney Bar ID: 006691985
Attorney Email:

Defendants

Sanofi-Aventis U.S. Llc

Party Description: Corp
Phone:
Address Line 1: Corporation Service Company
Address Line 2: 100 Charles Ewing Blvd., Suite 160
City: Ewing
State: NJ
Zip: 08628
Attorney Name:
Attorney Bar ID:
Attorney Email:

Regeneron Pharmaceuticals Inc.

Party Description: Corp
Phone:
Address Line 1: Ct Corporation Systems
Address Line 2: 820 Bear Tavern Road
City: West Trenton
State: NJ
Zip: 08628
Attorney Name:
Attorney Bar ID:
Attorney Email:

ACMS Documents

Filed Date	Doc Number	Document Type	Filing Party	Doc Status	CO ID	Type	Date Served	Service Status	Party Served
06/11/2026	001	COMP JRY DEMAND	DOUGLAS						

Case Actions

Filed Date	Docket Text	Transaction ID	Entry Date
06/11/2026	Complaint with Jury Demand for ATL-L-001199-26 submitted by RELKIN, ELLEN , WEITZ & LUXENBERG PC on behalf of WILLIAM DOUGLAS against SANOFI-AVENTIS U.S. LLC, REGENERON PHARMACEUTICALS INC.	LCV20261564421	06/11/2026

Wolters Kluwer

CT Corporation
Service of Process Notification
06/11/2026
CT Log Number 552463851

Service of Process Transmittal Summary

TO: Adam Bernstein, Director
Regeneron Pharmaceuticals, Inc.
777 OLD SAW MILL RIVER ROAD
TARRYTOWN, NY 10591

RE: **Process Served in New Jersey**

FOR: REGENERON PHARMACEUTICALS, INC. (Domestic State: NY)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: WILLIAM DOUGLAS // To: REGENERON PHARMACEUTICALS, INC.
CASE #:	ATLL00119926
NATURE OF ACTION:	Product Liability Litigation - Drug Litigation
PROCESS SERVED ON:	C T Corporation System, West Trenton, NJ
DATE/METHOD OF SERVICE:	By Process Server on 06/11/2026 at 11:55
JURISDICTION SERVED:	New Jersey
ACTION ITEMS:	CT will retain the current log Image SOP Email Notification, Larry Bliss larry.bliss@regeneron.com Email Notification, Larry Coury larry.coury@regeneron.com Email Notification, Doris Avendanoweber doris.avendanoweber@regeneron.com Email Notification, Arunabha Bhoumik arunabha.bhoumik@regeneron.com Email Notification, James Evans james.evans@regeneron.com Email Notification, Petra Scamborova petra.scamborova@regeneron.com Email Notification, Adam Bernstein adam.bernstein@regeneron.com Email Notification, MELISSA LOZNER melissa.lozner@regeneron.com Email Notification, Meghan Larywon meghan.larywon@regeneron.com
REGISTERED AGENT CONTACT:	C T Corporation System 820 Bear Tavern Road West Trenton, NJ 08628 866-401-8252 LargeCorporationTeam@wolterskluwer.com

PROCESS SERVER DELIVERY DETAILS

Date: Thu, Jun 11, 2026
Server Name: Remy Nicoletti

Entity Served	REGENERON PHARMACEUTICALS, INC.
Case Number	ATL-L-001199-26
Jurisdiction	NJ

Inserts		

WEITZ & LUXENBERG
A New York Professional Corporation
220 Lake Drive East, Suite 210
Cherry Hill, NJ 08002
Telephone No. (856) 755-1115

WILLIAM DOUGLAS,	SUPERIOR COURT OF NEW JERSEY
	LAW DIVISION
Plaintiff(s),	ATLANTIC COUNTY
v.	
	DOCKET NO.: ATL-L-001199-26
SANOFI-AVENTIS U.S. LLC,	CIVIL ACTION
GENZYME CORPORATION,	
REGENERON PHARMACEUTICALS, INC.	
Defendant(s).	**SUMMONS**

From the State of New Jersey
TO THE DEFENDANT NAMED BELOW

From the State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (The address of each deputy clerk of the Superior Court is provided.) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, CN-971, Trenton, NJ 08625-0971. A filing fee payable to the [Clerk of the Superior Court] Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of $135.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live. A list of these offices is provided. If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A list of these numbers is also provided.

Dated: June 11, 2026

/s/ Michelle M. Smith
Michelle M. Smith, Clerk of the Superior Court

Name and Address of Defendant to be Served:

REGENERON PHARMACEUTICALS, INC.
C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

Ellen Relkin (Attorney ID # 006691985)
Laura J. Baughman (pro hac vice application forthcoming)
WEITZ & LUXENBERG
A New York Professional Corporation
220 Lake Drive East, Suite 210
Cherry Hill, New Jersey 08002
P: 856-755-1115 F: 856-755-1995
erelkin@weitzlux.com

Attorneys for Plaintiff

COMPLAINT

WILLIAM DOUGLAS, ***Plaintiff,*** ***vs.*** **SANOFI-AVENTIS U.S. LLC and REGENERON PHARMACEUTICALS, INC.,** ***Defendants.***	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY** **Docket No.:** **CIVIL ACTION** **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**

COMES NOW Plaintiff, William Douglas, by and through undersigned counsel, and hereby brings this action for damages against Defendants Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc., and alleges as follows:

INTRODUCTION

1. This is an action for damages due to Plaintiff relating to Defendants' development, testing, manufacture, packaging, preparation, labeling, marketing, supply and/or sale of the dangerous and defective pharmaceutical product Dupixent®.

2. Defendants misrepresented that Dupixent was a safe and effective treatment for

atopic dermatitis and other inflammatory health conditions when in fact the drug causes cutaneous T-cell lymphoma (CTCL), a form of non-Hodgkin's lymphoma, and/or triggers a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

3. Defendants failed to warn physicians and the public about Dupixent's propensity to cause CTCL or rapidly exacerbate subclinical CTCL.

4. Consumers and physicians alike have been misled about the safety and efficacy of Dupixent, and as a result consumers, including Plaintiff, have developed CTCL.

PARTIES

5. Plaintiff William Douglas was a resident of Memphis, Shelby County, Tennessee during the time frame when he took Dupixent and at all times relevant hereto.

6. Defendant, Sanofi-Aventis U.S. LLC (hereinafter "Sanofi-Aventis"), is and was at all times relevant hereto a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis is a wholly-owned subsidiary of Sanofi US Services, Inc., a Delaware corporation.

7. Upon information and belief, Defendant Sanofi-Aventis has been substantively involved in, *inter alia*, the development and sale of Dupixent and the design, funding, conduct, authorship, publication and dissemination of scientific research and promotional messaging related to Dupixent and the indications for which Dupixent has received approval to treat.

8. Defendant Regeneron Pharmaceuticals, Inc. (hereinafter "Regeneron") is and was at all times relevant hereto a corporation organized under the laws of the state of New York with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

9. Defendant Regeneron is registered to do business in New Jersey and established an

agent to receive service of process at CT Corporation System, at 820 Bear Tavern Road, West Trenton, NJ 08628.

10. Defendant Regeneron has a large 127,000 square foot corporate campus located at 300 Warren Corporate Center Drive in Warren, New Jersey where key functions are conducted including Strategic Planning & Execution; Product Management; Delivery; Operations, Clinical Database Development; Global Patient Safety, and IT. Regeneron boasts "Our Warren location is surrounded by lush greenery, offering a serene, park-like atmosphere perfect for breakthrough thinking. With amenities such as a state-of-the-art gym, a cozy café, and plenty of open spaces to recharge, Warren is where productivity meets tranquility."[1]

11. Defendant Regeneron has conducted and still conducts clinical trials relating to Dupixent in New Jersey including an ongoing trial for atopic dermatitis which is recruiting patients at the Eczema Treatment Center in East Windsor, New Jersey as well as other facilities in Edison and Piscataway, New Jersey.[2]

12. Defendant Regeneron employs and recruits in New Jersey sales representatives, now known as "Medical Specialists," charged with "Developing strategy and executing tactics within key accounts in the Dermatology therapeutic area" and "establishing and fostering strong

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[1] Warren, NJ, Regeneron Careers, https://careers.regeneron.com/en/locations/north-america/warren-nj/ (last visited Mar. 30, 2026); Locations, Regeneron Pharms., Inc., https://www.regeneron.com/about/our-company/locations (last visited Mar. 30, 2026); Joshua Burd, Regeneron Takes 127,000 Sq. Ft. at Vision's Warren Corp. Ctr., Real Est. NJ (Apr. 22, 2024), https://re-nj.com/regeneron-takes-127000-sq-ft-at-visions-warren-corporate-center/ ; Sr. Mgr., EDC Dev., Director, Prod. Mgmt. Delivery Operations, & Director, Glob. Patient Safety Scis. (Gen. Med.), Regeneron Careers, https://careers.regeneron.com/es/trabajos/r45329/sr-mgr-edc-development/ , https://careers.regeneron.com/en/jobs/r45153/director-product-management-delivery-operations/ , https://careers.regeneron.com/en/jobs/r45803/director-global-patient-safety-sciences-general-medicine/ (last visited Mar. 30, 2026).

[2] [2] *Clinical Trial NCT05285839 & Clinical Trial NCT03428646*, Regeneron Clinical Trials, https://clinicaltrials.regeneron.com/clinical-trials/a0MPr0000005iRlMAI/nct05285839, https://clinicaltrials.regeneron.com/clinical-trials/a0MPr0000005iOjMAI/nct03428646 (last visited Mar. 30, 2026).

working relationships with health care professionals, including nurses, office staff key patient advocacy support groups."[3]

13. Defendant Regeneron is the current official sponsor of the Biologics License Application (BLA) for Dupixent in the United States and thus maintains significant responsibility and control over the drug and all activities and materials relating thereto. Defendant Regeneron has been substantively involved in the development and sale of Dupixent and the design, funding, conduct, authorship, publication and dissemination of scientific research and promotional messaging related to Dupixent and the indications for which Dupixent has received approval to treat.

14. Defendants Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. shall hereinafter be referred to collectively as "Defendants".

15. Defendants, directly and/or through third parties acting upon Defendants' directives, were jointly engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Dupixent and controlling the Biologics License Application for Dupixent and other intellectual property associated with Dupixent.

16. At all times relevant hereto, Defendants include and have included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

17. At all times relevant hereto, Defendants were engaged in the business of

[3] *Med. Specialist I—Dermatology (Morristown, N.J.)*, Regeneron Careers, https://careers.regeneron.com/en/jobs/r45006/medical-specialist-i-dermatology-morristown-nj/ (last visited Mar. 30, 2026).

developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, and in the states of New Jersey and Tennessee, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the pharmaceutical product Dupixent.

JURISDICTION & VENUE

18. This Court has jurisdiction over the subject matter of this action under the New Jersey Constitution Article VI, § 3, paragraph 2.

19. The causes of action alleged in this Complaint arise out of or relate to the Defendants' activities in and contacts within New Jersey.

20. Plaintiff is and at all relevant times has been a resident of Memphis, Tennessee.

21. Substantial activities relating to the design, development, marketing, labeling, warnings, promotion, and sale of Dupixent were conducted by Defendants throughout the State of New Jersey. Likewise, substantial activities relating to the funding, conduct, authorship, publication, and dissemination of scientific research and promotional messaging concerning Dupixent were carried out in New Jersey.

22. Each Defendant is authorized to transact business in New Jersey and has purposefully availed itself of the privilege of conducting substantial business activities within the State. Defendants regularly conduct and solicit business in New Jersey and derive substantial revenue from the sale of Dupixent in this State.

23. Defendants have sufficient minimum contacts with New Jersey such that maintenance of the suit does not offend traditional notions of fair play and substantial justice.

24. Defendant Sanofi-Aventis U.S. LLC. has its principal place of business in Bridgewater, New Jersey.

25. Although Defendant Regeneron Pharmaceuticals, Inc. is a nonresident of New Jersey, this Court has personal jurisdiction pursuant to, and consistent with, New Jersey's long-arm jurisprudence and the requirements of Due Process.

26. Venue is proper in Atlantic County, New Jersey, pursuant to R. 4:3-2 as all Defendants do business in Atlantic County and all counties in New Jersey.

GENERAL ALLEGATIONS

27. This action is for damages brought on behalf of Plaintiff William Douglas**,** who was prescribed and supplied with and who has taken the prescription drug Dupixent, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, or otherwise placed in the stream of commerce by Defendants.

28. Plaintiff was prescribed Dupixent to treat eczematous dermatitis. Plaintiff was injected with Dupixent from approximately January 2025 until September 2025. Plaintiff was diagnosed with mycosis fungoides, a subtype of CTCL, in or about September 2025.

29. Plaintiff William Douglas brings this action against Defendants to recover damages for the injuries suffered as a result of his use of Dupixent and to recover for his individual economic and non-economic damages which he sustained as a result therefrom.

30. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

31. At all times relevant, Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale the prescription drug Dupixent for use by physicians in treating their patients, including

Plaintiff.

32. At all times relevant hereto, Defendants were authorized to do business within Plaintiff's state of residence and did conduct such business.

33. At times relevant hereto, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of Dupixent when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of Dupixent and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff discussed herein.

FACTS COMMON TO ALL COUNTS

A. Dupixent

34. Dupixent® (dupilumab) is a therapeutic biologic used in the treatment of infants, children and adults with inflammatory health conditions in the United States and worldwide.

35. Dupixent is a human monoclonal immunoglobulin G4 antibody that binds to the interleukin (IL)-4 receptor alpha subunit shared by IL-4 and IL-13 to prevent their signaling. IL-4 and IL-13 signaling produces an inflammatory cascade that has been implicated in a number of immune-mediated inflammatory conditions, including atopic dermatitis, chronic rhinosinusitis with nasal polyposis, eosinophilic esophagitis, prurigo nodularis, chronic obstructive pulmonary disease, chronic spontaneous urticaria and bullous pemphigoid. Despite this, the mechanism of action through which Dupixent exerts a therapeutic effect in patients with these conditions has not been definitively established.

36. Dupixent is supplied by Defendants in 200 mg and 300 mg single-dose prefilled syringes and single-dose prefilled pens. Dupixent is administered by patients or by caregivers through a subcutaneous injection in 1-, 2- or 4-week intervals depending on age, weight and

therapeutic indication.

B. Defendants' Collaboration Agreement

37. In November 2007, Defendant Regeneron entered into a License and Collaboration Agreement with Sanofi, via its subsidiaries and/or affiliate entities. Under this License and Collaboration Agreement, Sanofi agreed to provide research funding in exchange for exclusive rights to co-develop and co-commercialize any new biopharmaceuticals discovered by Defendant Regeneron. Defendants contemporaneously entered into a Discovery and Preclinical Development Agreement under which Defendant Regeneron would discover and create products for joint development and commercialization with Sanofi and its subsidiaries and/or affiliates.

38. In November 2009, Defendant Regeneron and Sanofi, via its subsidiaries and/or affiliate entities, expanded the scope and terms of their collaboration in an Amended and Restated License and Collaboration Agreement and Amended and Restated Discovery and Preclinical Development Agreement. The Amended and Restated License and Collaboration Agreement currently remains in effect, with subsequent amendments in May 2013, July 2015, April 2020 and September 2021, while the Amended Discovery Agreement expired in 2017.

39. One of the drugs Defendants agreed to co-commercialize under the Amended and Restated License and Collaboration Agreement was Dupixent. Sanofi via its subsidiary and/or affiliate entities provided upfront funding to cover 100% of the costs incurred by Defendant Regeneron in the development of Dupixent and other Licensed Products under the Amended and Restated License and Collaboration Agreement, including an initial non-refundable sum of $85 million USD.

40. Sanofi, individually and/or through its subsidiaries, is considered the lead party with respect to the commercialization of Dupixent, and Defendant Regeneron exercised its co-

promotion rights under the Restated License and Collaboration Agreement for Dupixent in the United States.

41. Sanofi, individually and/or through its subsidiary, Defendant Sanofi-Aventis, continues to supply funding for ongoing Dupixent development research being conducted by Defendant Regeneron.

42. Upon information and belief, Defendants Sanofi-Aventis and Regeneron, both independently and collaboratively, are substantively involved in performing commercialization activities for Dupixent in the United States, including but not limited to manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising, along with support activities associated with each of those functions, both directly and through third parties acting on their behalf.

43. Under the terms of the Amended and Restated License and Collaboration Agreement, Defendants have a reciprocal duty to regularly share information relating to the commercialization of Dupixent, to include anticipated launch dates, key market metrics, market research and sales, as well as to promptly notify the other party of any major market developments.

44. Sanofi, the parent company of Defendant Sanofi-Aventis, recognizes all sales of Dupixent. Profits and losses arising from commercial operations in the United States, including those associated with Dupixent, are split equally (50/50) between Sanofi and its subsidiaries and Defendant Regeneron. Profit-sharing between Defendants for sales of Dupixent outside of the United States is done based on a sliding scale. Defendant Regeneron also receives or has at times received milestone payments from Sanofi based on sales of Dupixent and other Licensed Products in markets outside of the United States.

45. Upon information and belief, Sanofi serves as the "Lead Regulatory Party", as

defined in the Amended and Restated License and Collaboration Agreement, responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies for Dupixent in the United States. Further upon information and belief, Defendant Sanofi-Aventis handles all processing and submissions of adverse event reports and product complaints for Dupixent in the United States on behalf of Sanofi. Despite this, Defendants have joint responsibility under the terms of the Amended and Restated License and Collaboration Agreement to collaborate in fulfilling all regulatory requirements concerning pharmacovigilance and risk management plans and product complaint reporting associated with Dupixent in the United States. Further to this joint responsibility, upon information and belief, Defendants executed a Safety Data Exchange Agreement setting forth the specific procedures to be used to coordinate the investigation and exchange of reports of adverse events and complaints associated with Dupixent to ensure timely communication to regulatory authorities and compliance with applicable laws as prescribed in the Amended and Restated License and Collaboration Agreement.

C. Development of Dupixent

46. Upon information and belief, the human monoclonal antibody and active ingredient in Dupixent, dupilumab, formerly known under the common names REGN668 and SAR231893, was originally discovered by Defendant Regeneron during the mid- to late-2000s. Defendant Regeneron utilized its proprietary VelocImmune® technology, a genetically-engineered mouse platform endowed with a genetically-humanized immune system, in order to invent dupilumab.

47. Defendant Regeneron has been assigned at least 7 United States patents relating to Dupixent, including US 7,608,693 B2 (October 2009), US 8,735,095 B2 (May 2014), US 8,945,559 B2 (February 2015), US 9.238,692 B2 (January 2016), US 10,435,473 B2 (October 2019), US 11,059,896 B2 (July 2021) and US 11,926,670 (March 2024).

48. The first clinical development program for Dupixent in the treatment of patients with atopic dermatitis was regulated under Investigational New Drug ("IND") Application number 107969 in the United States. Defendant Regeneron submitted IND number 107969 to the United States Food and Drug Administration ("FDA") on July 12, 2010 requesting permission to study Dupixent in human subjects. The FDA deemed the first Phase I clinical study to assess the safety and tolerability of Dupixent in adult patients with atopic dermatitis "Safe to Proceed" on August 21, 2010.

49. During clinical development, the FDA granted Dupixent a Breakthrough designation, Priority Review and Rolling Review, regulatory programs which are each intended to expedite development and approval of new therapeutics. Defendant Regeneron completed its rolling submission of Biologics License Application ("BLA") number 761055 for Dupixent to FDA on July 28, 2016. FDA received the BLA on July 29, 2016.

50. Defendants officially received FDA approval to market Dupixent in the United States on March 28, 2017 for the treatment of adult patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

51. The original approval of Dupixent was based on the results of three Phase III randomized controlled trials, SOLO 1, SOLO 2, and CHRONOS, which used a clinical scale known as the Investigator's Global Assessment (IGA) to measure changes in atopic dermatitis disease severity in response to treatment. Each of these trials demonstrated superiority of Dupixent over placebo or placebo plus topical corticosteroids in the primary endpoint, change from baseline to Week 16 in the proportion of subjects achieving an IGA score of 0 (clear skin) or 1 (almost clear skin), with at least a 2-point improvement in IGA score.

52. Following its approval in March 2017 as a second-line treatment for adult patients with atopic dermatitis in the United States, Defendants proceeded to submit several supplemental BLAs to the FDA seeking to market Dupixent for the treatment of additional health conditions and expand the indicated patient population to include nearly all age groups.

53. Dupixent is now indicated for the treatment of atopic dermatitis (AD), asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE) and chronic spontaneous urticaria in adult and pediatric patients and for the treatment of prurigo nodularis (PN), chronic obstructive pulmonary disease (COPD) and bullous pemphigoid in adult patients.

54. Defendants continue to co-develop Dupixent under INDs in the treatment of chronic pruritus of unknown origin, eosinophilic gastritis with or without eosinophilic duodenitis, lichen simplex chronicus and ulcerative colitis.

D. Defendants' Marketing of Dupixent

55. Defendants have utilized multiple mediums and mechanisms including in television advertisements, social media, the internet, and print brochures to aggressively promote Dupixent as a necessary, life-changing therapy for patients suffering from atopic dermatitis and other inflammatory health conditions in order to drive prescriptions. Much of Defendants' approach to boosting Dupixent uptake has involved expanding the market for its use by convincing individuals with subtle to no symptoms that they actually have a serious, undiagnosed inflammatory health condition, and penetrating the existing market by convincing patients that their current treatment regimen is inadequate to control their disease and/or has an unacceptable safety profile.

56. Defendants have infused billions of dollars into persuasive direct-to-consumer advertising depicting Dupixent as being highly safe and effective and capable of greatly improving the quality of patients' lives.

57. In 2024, Defendants spent an estimated $484.1 million on advertising for Dupixent across all media types. This spend included $276 million on 17 different direct-to-consumer television advertisements: 8 for atopic dermatitis, 8 for asthma and 1 for gastrointestinal conditions. Defendants' annual advertising expenditures for Dupixent were the third highest among all marketed drugs in 2024.[4]

58. In 2023, Defendants spent an estimated $502 million on advertising for Dupixent across all media types. This spend included $315.3 million on 12 different direct-to-consumer television advertisements: 8 for atopic dermatitis and 4 for asthma. Defendants' annual advertising expenditures for Dupixent were the second highest among all marketed drugs in 2023.[5]

59. In 2022, Defendants spent an estimated $491 million on advertising for Dupixent across all media types. This spend included $305.9 million on direct-to-consumer television advertisements. Defendants' annual advertising expenditures for Dupixent were higher than any other marketed drugs in 2022.[6]

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[4] Andrea Park, *AbbVie Pulls Off a Hat Trick with 3rd Straight Year as Top TV Drug Ad Spender, Buoyed by Skyrizi and Rinvoq Spots*, Fierce Pharma (Jan. 22, 2025), https://www.fiercepharma.com/marketing/abbvie-pulls-hat-trick-3rd-straight-year-top-tv-drug-ad-spender-buoyed-skyrizi-and-rinvoq (last visited Dec. 9, 2025); Andrea Park, Nick Paul Taylor & Zoey Becker, *The Top 10 Pharma Drug Ad Spenders of 2024*, Fierce Pharma (June 30, 2025), https://www.fiercepharma.com/marketing/top-10-pharma-drug-ad-spenders-2024 (last visited Dec. 9, 2025).

[5] Ben Adams, Andrea Park & Nick Paul Taylor, *AbbVie Makes Clean Sweep—Skyrizi and Rinvoq Top TV Drug-Ad Spender for 2023*, Fierce Pharma (Jan. 9, 2024), https://www.fiercepharma.com/marketing/abbvie-makes-clean-sweep-skyrizi-and-rinvoq-top-tv-drug-ad-spender-2023 (last visited Dec. 9, 2025); Ben Adams, Andrea Park & Nick Paul Taylor, *The Top 10 Pharma Drug Ad Spenders for 2023*, Fierce Pharma (June 3, 2024), https://www.fiercepharma.com/marketing/top-10-pharma-drug-ad-spenders-2023 (last visited Dec. 9, 2025); Park, supra note 5, https://www.fiercepharma.com/marketing/abbvie-pulls-hat-trick-3rd-straight-year-top-tv-drug-ad-spender-buoyed-skyrizi-and-rinvoq ; Andrea Park, Nick Paul Taylor & Zoey Becker, *The Top 10 Pharma Drug Ad Spenders of 2024*, Fierce Pharma (June 30, 2025), https://www.fiercepharma.com/marketing/top-10-pharma-drug-ad-spenders-2024 (last visited Dec. 9, 2025).

[6] Ben Adams, *The Top 10 Pharma Drug-Brand Ad Spenders for 2022*, Fierce Pharma (May 1, 2023), https://www.fiercepharma.com/special-reports/top-10-pharma-drug-brand-ad-spenders-2022 (last visited Dec. 9, 2025).

60. In 2021, Defendants spent an estimated $523.9 million on advertising for Dupixent across all media types. This spend included $287.6 million on direct-to-consumer television advertisements. Defendants' annual advertising expenditures for Dupixent were higher than any other marketed drugs in 2021.[7]

61. In 2020, Defendants spent an estimated $409.8 million on advertising for Dupixent across all media types. This spend included millions on 7 different direct-to-consumer television advertisements: 4 for atopic dermatitis and 3 for asthma. Defendants' annual advertising expenditures for Dupixent were the second highest among all marketed drugs in 2020.[8]

62. In 2019, Defendants spent an estimated $199.4 million on their first full year of advertising for Dupixent across all media types. This spend included $76 million on direct-to-consumer television advertisements. Defendants' annual advertising expenditures for Dupixent were the third highest among all marketed drugs in 2019.[9]

63. In 2018, Defendants spent an estimated $104.2 million on direct-to-consumer advertising.[10]

64. Defendants' provocative messaging typically bombards consumers with glossy imagery and catchy phrases like "Du-More", "Better Days" and "This is Better" that imply patients will lead happier, more productive and more fulfilling lives if they use Dupixent. For patients with

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[7] *Id.*

[8] Beth Snyder Bulik, *The Top 10 Ad Spenders in Big Pharma for 2020*, Fierce Pharma (Apr. 19, 2021), https://www.fiercepharma.com/special-report/top-10-ad-spenders-big-pharma-for-2020 (last visited Dec. 9, 2025).

[9] Beth Snyder Bulik, *Pharma's 2019 TV Spending Ticks Up — Barely — Thanks to Big Humira Growth*, Fierce Pharma (Jan. 14, 2020), https://www.fiercepharma.com/marketing/pharma-tv-ad-spending-for-2019-finishes-flat-compared-to-previous-year (last visited Dec. 9, 2025); Beth Snyder Bulik, *The Top 10 Ad Spenders in Big Pharma for 2019*, Fierce Pharma (Feb. 19, 2020), https://www.fiercepharma.com/special-report/top-10-advertisers-big-pharma-for-2019 (last visited Dec. 9, 2025).

[10] U.S. Gov't Accountability Off., GAO-21-380, *Prescription Drugs: Medicare Spending on Drugs with Direct-to-Consumer Advertising: Report to the Committee on the Judiciary, U.S. Senate* (May 2021), https://www.gao.gov/assets/gao-21-380.pdf (last visited Dec. 9, 2025).

eczema, Defendants claim that Dupixent "help[s] heal your skin from within"[11] and "helps you feel the heal and see the difference with less itch and clearer skin."[12] They encouraged patients to "show off your skin."[13] For patients with asthma, Defendants claim that Dupixent "helps people with asthma breathe easier" and will allow them to "get more out of [their] lungs," to "Du [sic] more with less asthma" and "achieve better breathing that lasts."[14] Defendants promote Dupixent as providing "Benefits with every breath."[15] For patients with COPD, Defendants claim that Dupixent is "proven to help reduce flareups so you can do more with less COPD" and that it "helps adults breathe easier starting in as little as two weeks. That could mean more places visited, more dogs walked, more gardens tended, more to look forward to. It's amazing what can happen when you can do more."[16]

65. According to a spokesperson for Defendant Regeneron, one 60-second Dupixent commercial that aired throughout 2024 made patients "not only want to talk to their doctors but also to rewatch the ad".[17]

66. To ensure ready access to Dupixent and prevent potential sales lapses from treatment

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[11] Dupixent Patient Brochure, 2023, Sanofi and Regeneron Pharmaceuticals, Inc., "Stay ahead of eczema with Dupixent"; Dupixent "No Matter What" TV spot, https://www.andrewjeske.com/dupixent; Dupixent "Stay Ahead" TV spot, https://www.ispot.tv/ad/50Bs/dupixent-stay-ahead; Dupixent "Show Off: Pool and Party" TV spot, https://www.ispot.tv/ad/6Jz9/dupixent-show-off-pool-and-party; Dupixent "One Step Ahead" TV spot, https://www.ispot.tv/ad/OGzj/dupixent-one-step-ahead.

[12] *E.g.*, Dupixent Patient Brochure, 2025, Sanofi and Regeneron Pharmaceuticals, Inc., "Dupixent helps you feel the heal and see the difference." *See also* https://www.dupixent.com/atopicdermatitis/.

[13] *E.g.*, Dupixent "Show Off: Pool and Party" TV spot, https://www.ispot.tv/ad/6Jz9/dupixent-show-off-pool-and-party.

[14] Dupixent TV Spot, "Better Days", https://www.ispot.tv/ad/BTY3/dupixent-asthma-better-days; Dupixent TV Spot, "This is Better: Roller Disco", https://www.ispot.tv/ad/TRbU/dupixent-this-is-better-roller-disco. *See also* https://www.dupixent.com/asthma/.

[15] https://www.dupixent.com/asthma/.

[16] Dupixent TV Spot, "More", https://www.ispot.tv/ad/Tj_6/dupixent-more. *See also* https://www.dupixent.com/copd/.

[17] Andrea Park, Nick Paul Taylor & Zoey Becker, *The Top 10 Pharma Drug Ad Spenders of 2024*, Fierce Pharma (June 30, 2025), https://www.fiercepharma.com/marketing/top-10-pharma-drug-ad-spenders-2024 (last visited Dec. 9, 2025).

interruptions or omissions, Defendants launched Dupixent MyWay, a support program that helps patients "get access to DUPIXENT and stay on track".[18] Defendants paired Dupixent MyWay with the Dupixent MyWay Ambassador program which uses real world patients to endorse and further disseminate their messaging. Defendants also created and launched smartphone apps, EZTtrack for Atopic Dermatitis and the Dupixent MyWay Patient App, to help patients access Dupixent "as quickly as possible" and facilitate "more productive conversations" with doctors that are more likely to lead to a prescription for Dupixent.[19,20]

67. In conjunction with branded advertising, Defendants have amplified public awareness of the conditions for which Dupixent is indicated in order to increase rates of their diagnosis and further drive prescriptions of Dupixent. Defendants accomplished this by using unbranded disease state awareness websites and funding and conducting large-scale unbranded disease state awareness campaigns, scientific publications and continuing medical education programs. With these multifaceted unbranded campaigns, which Defendants designed to track branded marketing campaigns, Defendants began seeding the market for Dupixent well before it received FDA approval for marketing in the United States.

68. Defendant Regeneron initially registered the disease state awareness website UnderstandAD.com on March 23, 2016 and continues to own and operate it in conjunction with Defendant Sanofi-Aventis and the National Eczema Association. Also on March 23, 2016, Sanofi, under its former name Sanofi-Synthelabo, initially registered the disease state awareness website EczemaExposed.com, which is currently hosted by Defendant Sanofi-Aventis. Defendants use

[18] DUPIXENT MyWay, *Patient Support Program*, dupixent.com, https://www.dupixent.com/support-savings/dupixent-my-way (last visited Dec. 9, 2025).
[19] Apple Inc., *MyWay Patient Support*, Apple App Store, https://apps.apple.com/us/app/myway-patient-support/id6443848439 (last visited Dec. 9, 2025).
[20] Apptopia, About — *MyWay Patient Support (iOS),* Apptopia, https://apptopia.com/ios/app/1501488844/about (last visited Dec. 9, 2025).

these disease state awareness websites to provide seemingly unbiased educational information geared towards highlighting the potential burdens of atopic dermatitis on patients, helping patients identify signs and symptoms of undiagnosed atopic dermatitis and suggesting to patients that their condition is more uncontrolled than they might believe, while also supplying guidance to steer productive communications with physicians regarding available treatment options. Upon information and belief, Defendants registered these web domains approximately one week before making their first rolling submission of the Dupixent BLA to the FDA.

69. In Defendant Regeneron's November 2017 Earnings Call, Defendants acknowledged their goal to increase rates of diagnosis and further drive prescriptions of Dupixent. Robert J. Terifay, Regeneron's Executive Vice President, Commercial, stated "we anticipate is that we will see other prescribers as patients become aware through our direct-to-consumer campaign on the severity of the condition and the need to seek out a dermatologist, and that there could be an increased urgency to treat over time".[21] During this call, Defendants also represented prescriptions are not driven from physicians but rather ". . .expansion into moderate AD . . . helped by our direct-to-consumer campaign".[22]

70. Defendants' vast unbranded marketing campaigns for other indicated conditions have followed suit. Another disease state awareness website targeting asthma and chronic rhinosinusitis with nasal polyps, TheNextBreath.com, was originally registered by Sanofi, under its former name Sanofi-Synthelabo, and is currently maintained by Defendant Regeneron and Sanofi, individually and/or through its subsidiaries. Through this website Defendants aim to "bring more awareness to severe asthma" and "empower people to take action to strive for better asthma

[21] Regeneron Pharm., Inc., Q3 2017 Earnings Call Transcript, ROIC.AI (Nov. 8, 2017), https://www.roic.ai/quote/REGN/transcripts/2017/3
[22] *Id.*

control", while claiming asthma "often goes unrecognized". Additionally, Defendants cite statistics such as "[o]ver 80% of people overestimate how well controlled their asthma is" and nearly half of asthma patients "have symptoms that are not well controlled", as a means to convince patients that believe they have "good" or "very good" control over their asthma symptoms that they are actually wrong.

71. Another disease state awareness website, Type2Inflammation.com, was originally registered by Sanofi, under its former name Sanofi-Synthelabo, in February 2019 and is currently maintained by Defendant Sanofi-Aventis on behalf of Defendants. Defendants utilize this unbranded website to drive awareness and treatment of several conditions for which Dupixent has been approved, including eosinophilic esophagitis, chronic spontaneous urticaria, prurigo nodularis, atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis and chronic obstructive pulmonary disease.

72. Finally, Defendants own and maintain two disease state awareness websites dedicated to driving awareness and treatment of chronic obstructive pulmonary disease: ThinkCOPDInflammation.com, initially registered in March 2023 by Sanofi, under its former name Sanofi-Synthelabo, and currently maintained by Defendant Regeneron and Sanofi, individually and/or through its subsidiaries; and LiveWithCOPD.com, initially registered in December 2023 by Sanofi, under its former name Sanofi-Synthelabo, and currently maintained by Defendant Sanofi-Aventis on behalf of Defendants. Upon information and belief, Defendants registered the web domain ThinkCOPDInflammation.com approximately 9 months before submitting the supplemental BLA for Dupixent in the treatment of COPD to the FDA, and Defendants registered the web domain LiveWithCOPD.com approximately 2 weeks before submitting the supplemental BLA for Dupixent in the treatment of COPD to the FDA.

73. On July 12, 2016, Defendants Sanofi-Aventis and Regeneron launched the "Understand AD" awareness campaign which was "focused on educating people about moderate-to-severe atopic dermatitis".[23] Defendants highlighted extreme examples of symptoms to depict how uncontrolled atopic dermatitis can impact patients' lives and utilized celebrity chef Elizabeth Falkner as a spokesperson to expand the reach and influence of this initiative. In a press release about the Understand AD campaign, Defendants specifically signaled "there is still a need for additional treatment options for atopic dermatitis." Upon information and belief, Defendants launched this disease state awareness campaign approximately 2 weeks before making their final rolling submission of the Dupixent BLA to the FDA.

74. On October 11, 2017, Defendants Sanofi-Aventis and Regeneron launched the campaign "Understand AD: A Day in the Life" using Peter Moffat, writer and executive producer of the HBO show "The Night Of" to help push their unbranded disease awareness messaging for the stated purpose of "Driving Empathy and Understanding" of atopic dermatitis.[24] In the spirit of disease mongering, Defendants represented that this program would serve to "transport[] people into what a typical, often unremitting and painful day is really like for people living with uncontrolled moderate-to-severe atopic dermatitis". Taking care not to explicitly reference Dupixent, Defendants also casually highlighted that atopic dermatitis patients often "continue to experience debilitating symptoms despite available topical and systemic steroid treatment options, causing their disease to remain uncontrolled" in the press release announcing this campaign.

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[23] Regeneron Pharmaceuticals, Inc., *Award-Winning Chef Elizabeth Falkner Reveals Her Struggle with Atopic Dermatitis to Highlight the Physical and Psychological Impact of the Disease* (news release), Regeneron Investor Relations (July 12, 2016), https://investor.regeneron.com/news-releases/news-release-details/award-winning-chef-elizabeth-falkner-reveals-her-struggle-atopic (last visited Dec. 9, 2025).

[24] Regeneron Pharmaceuticals, Inc., *Internationally Acclaimed Writer and Executive Producer of HBO's "The Night Of" Partners With Regeneron to Release "Understand AD: A Day in the Life"* (news release), Regeneron Investor Relations (Oct. 11, 2017), https://investor.regeneron.com/static-files/4e57c3b2-9384-451d-b508-5e41052cb738 (last visited Dec. 9, 2025).

75. Then in September 2019 Defendants expanded the Understand AD program into its next phase, The Understand AD Squad video series, which was "targeted to adolescents with AD and their caregivers".[25] In the press release announcing the Understand AD Squad video series, Defendants exaggerated the rates and typical burdens of uncontrolled atopic dermatitis, suggesting "400,000 adolescents in the U.S. with uncontrolled moderate-to-severe atopic dermatitis" experience "debilitating, burdensome disease symptoms including intense, persistent itching, skin lesions and skin dryness, cracking, redness, crusting and oozing".

76. The next step of Defendants' calculated marketing efforts involved using published scientific literature to promote perceptions that patients suffering from atopic dermatitis are not being diagnosed or, if they have already received a diagnosis of atopic dermatitis, they are not being sufficiently treated.

77. Defendants wasted no time in strategizing Dupixent sales. Regeneron's Executive Vice President, Commercial, Robert J. Terifay, stated the month before FDA approval: "Sanofi Genzyme and Regeneron have fully hired and trained our field teams".[26]

78. In April 2017, the month following FDA approval of Dupixent for marketing in the United States, Defendants Sanofi-Aventis and Regeneron funded and published a cross-sectional survey study via several of their employees to prompt increases in atopic dermatitis diagnoses and prescriptions of atopic dermatitis therapies.[27] Published in American Journal of Clinical

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[25] Regeneron Pharmaceuticals, Inc., *Internationally Acclaimed Writer and Executive Producer of HBO's "The Night Of" Partners With Regeneron to Release "Understand AD: A Day in the Life"* (news release), Regeneron Investor Relations (Oct. 11, 2017), https://investor.regeneron.com/static-files/4e57c3b2-9384-451d-b508-5e41052cb738 (last visited Dec. 9, 2025).

[26] Regeneron Pharm., Inc., Q4 2016 Earnings Call Transcript, ROIC.AI (Feb. 23, 2017), https://www.roic.ai/quote/REGN/transcripts/2016-year/4-quarter (last visited Nov. 25, 2025).

[27] Wei W, Anderson P, Gadkari A, et al. Discordance Between Physician- and Patient-Reported Disease Severity in Adults with Atopic Dermatitis: A US Cross-Sectional Survey. Am J Clin Dermatol. 2017;18(6):825-835. doi:10.1007/s40257-017-0284-y

Dermatology, Defendants' study reported that awareness and use of clinical scales to measure atopic dermatitis severity was low, "suggesting a need for greater education of physicians regarding the availability and use of such measures for the assessment of AD". Despite nearly 70% concordance between patients and physicians on symptom severity, Defendants' employees concluded their results "show[ed] a discordance between patient- and physician-reported AD severity" and suggested "physicians may have a similar misunderstanding of the patient's perspective regardless of specialty". It was also the opinion of the authors that "clinical assessment may be less than optimal" and that "physicians may not be having meaningful conversations with patients about [quality of life] or the impact of AD on the daily life of the patient. The patient impact likely represents an important indicator of a need for treatment". Finally, the authors advised that it is important to include the patient perspective when making management decisions.

79. Defendants Sanofi-Aventis and Regeneron then funded and published a pair of studies in November 2017 and July 2018 in order to create and push a narrative that a majority of patients with atopic dermatitis continue to experience inadequate control of their symptoms despite treatment with therapies other than Dupixent, in addition to suffering from impaired quality of life and higher rates of anxiety, depression, work impairment, sleep impairment and itching symptoms.[28,29]

80. Defendants Sanofi-Aventis and Regeneron further endeavored to invent their own diagnostic tool for self-administration by patients. Defendants designed their 6-item patient symptom questionnaire, the Atopic Dermatitis Control Tool (ADCT), to have much greater

[28] Wei W, Anderson P, Gadkari A, et al. Extent and consequences of inadequate disease control among adults with a history of moderate to severe atopic dermatitis. J Dermatol. 2018;45(2):150-157. doi:10.1111/1346-8138.14116

[29] Simpson EL, Guttman-Yassky E, Margolis DJ, et al. Association of Inadequately Controlled Disease and Disease Severity With Patient-Reported Disease Burden in Adults With Atopic Dermatitis. JAMA Dermatol. 2018;154(8):903-912. doi:10.1001/jamadermatol.2018.1572

sensitivity than existing tools, and as a result, its use by patients would serve to artificially increase rates of atopic dermatitis diagnoses. Defendants funded and published a pair of studies in November 2019 and December 2019 in order to introduce the ADCT.[30,31] The ADCT tool has a dedicated website (adcontroltool.com) owned by Sanofi and maintained by Defendants Sanofi-Aventis and Regeneron, and is currently available for patients to use on Defendants' unbranded website EczemaExposed.com. Defendants created similar questionnaires to use with and increase diagnoses of atopic dermatitis in children aged 6 to 11 years, the Worst Itch Scale, and children and infants aged 6 months to less than 6 years, the Worst Scratch Itch Numeric Rating Scale (WSI-NRS).[32,33]

81. Finally, Defendants have funded and promoted hundreds of continuing medical education programs as a means to disseminate seemingly unbiased unbranded disease state awareness marketing materials directly to healthcare providers to increase screening and diagnoses of atopic dermatitis, asthma and other indicated health conditions and corresponding prescriptions of Dupixent. Defendants further established ADVENT, a dedicated global medical education platform disseminating "non-promotional" information to healthcare providers worldwide regarding Type 2 inflammatory diseases that Dupixent has been approved to treat or in which Dupixent is currently being investigated.[34]

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[30] Simpson E, Eckert L, Gadkari A, et al. Validation of the Atopic Dermatitis Control Tool (ADCT©) using a longitudinal survey of biologic-treated patients with atopic dermatitis. BMC Dermatol. 2019;19(1):15. Published 2019 Nov 6. doi:10.1186/s12895-019-0095-3

[31] Pariser DM, Simpson EL, Gadkari A, et al. Evaluating patient-perceived control of atopic dermatitis: design, validation, and scoring of the Atopic Dermatitis Control Tool (ADCT). Curr Med Res Opin. 2020;36(3):367-376. doi:10.1080/03007995.2019.1699516

[32] Paller AS, Yosipovitch G, Weidinger S, et al. Development, Psychometric Validation and Responder Definition of Worst Itch Scale in Children with Severe Atopic Dermatitis. Dermatol Ther (Heidelb). 2022;12(12):2839-2850. doi:10.1007/s13555-022-00804-z

[33] Paller AS, Siegfried E, Marron SE, et al. Development and validation of a caregiver-reported Numeric Rating Scale for measuring worst scratch/itch in patients aged 6 months to younger than 6 years with atopic dermatitis. J Am Acad Dermatol. 2024;90(2):382-385. doi:10.1016/j.jaad.2023.08.104

[34] ADVENT, *Welcome to ADVENT!*, https://www.adventprogram.com/us/ (last visited Dec. 9, 2025).

82. In addition to extensive branded and unbranded disease awareness marketing, Defendants have also leveraged influential third parties to inappropriately characterize the safety and effectiveness of Dupixent and promote its use in an unrestricted manner inconsistent with its FDA-approved indications. In this arm of the marketing scheme, Defendants partnered with patient advocacy organizations to further drive awareness of inflammatory health conditions and engaged and funded major academic societies, trade groups and leading subject matter experts who are charged with shaping clinical treatment guidelines.

83. Eight months before securing FDA approval to market Dupixent in the United States, Defendants Sanofi-Aventis and Regeneron, via the "Sanofi-Genzyme and Regeneron Alliance", funded and coordinated the convening of a "steering committee" to discuss and provide recommendations for the management of atopic dermatitis, later formalizing their opinions in a September 2017 publication termed a "Multidisciplinary Consensus" in The Journal of Allergy and Clinical Immunology: In Practice.[35] Oddly, the stated rationale for convening this "steering committee" was to "develop consensus recommendations relating to the diagnosis and treatment of patients with moderate-to-severe AD in the era of biologic therapies", even though at the time this "steering committee" met between July 2016 and January 2017, neither Dupixent nor any other biologic therapy had been approved for the treatment of atopic dermatitis. Although Dupixent was not an approved drug for any purpose at the time of the meeting, the "steering committee" nonetheless broadly advocated for its use in patients with atopic dermatitis, even beyond the indication that would eventually be approved by the FDA. Defendants used this publication as a vessel to position their experimental drug as the premier first-line therapy for

[35] Boguniewicz M, Alexis AF, Beck LA, et al. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. J Allergy Clin Immunol Pract. 2017;5(6):1519-1531. doi:10.1016/j.jaip.2017.08.005

patients with atopic dermatitis and to characterize its safety profile as being superior to existing therapies, including in terms of lymphoma risk, notwithstanding that it had not yet been used by any patients under real-world conditions. Indeed, in the discussion section of Defendants' treatment guidelines publication, the authors state "for patients with moderate-to-severe AD, the [steering committee] recommends dupilumab as a first-line systemic treatment option in adults". Of course, however, Dupixent has never been approved by the FDA as a first-line systemic treatment for atopic dermatitis, and instead is only indicated when patients first use and fail to respond to first-line topical treatments, rendering Dupixent a second-line, third-line or even fourth-line therapy. Nonetheless, making sure to drive the message home, the authors explicitly reiterate their recommendation for use of Dupixent as a "first-line systemic treatment" four (4) separate times in the publication. Additionally, the authors provide their opinion that all systemic immunosuppressive treatments commonly used for atopic dermatitis (cyclosporine, methotrexate, azathioprine and mycophenolate mofetil) are associated with an "increased risk" of lymphoma, while highlighting no such risk for Dupixent. The authors also stress the importance of ensuring patients have access to materials to educate themselves regarding atopic dermatitis therapies and that patient preference should play a major role in treatment selection.

84. Furthermore, a consultant for Defendants published an editorial in The Journal of Allergy and Clinical Immunology: In Practice to accompany and echo the recommendations of the "Multidisciplinary Consensus" article in which he characterized the use of Dupixent as "an example of precision medicine with minimal side effects and an avoidance of risks with antibiotics, systemic corticosteroids, and cytotoxic agents".[36]

85. Sanofi is a corporate sponsor of the International Eczema Council and currently

[36] Busse WW. Are Biotherapeutics Revolutionizing Treatment of "Allergic" Diseases?. J Allergy Clin Immunol Pract. 2017;5(6):1517-1518. doi:10.1016/j.jaip.2017.08.017

participates at the Director's Council level by providing $50,000 to $99,999 annually in unrestricted funding to the organization. Through its funding of the International Eczema Council, Sanofi and its subsidiaries receive certain important benefits, including yearly meetings with International Eczema Council leadership comprised of "the researchers and clinicians who are global influencers on atopic dermatitis research and treatment", active engagement in surveys and outreach from International Eczema Council leaders when considering policy decisions, participation in the International Eczema Council Industry Liaison Committee and the exclusive right of first refusal to participate in funding and shaping the International Eczema Council's special projects and fellowship opportunities. Despite its explicit designation as a second-line therapy in the FDA-approved prescribing information, the International Eczema Council conspicuously recommends Defendants' drug Dupixent as first-line therapy for patients with atopic dermatitis.[37,38,39]

86. Defendants Sanofi-Aventis and Regeneron are corporate sponsors of the American Academy of Dermatology Association and currently participate at the Diamond level by providing $500,000 or more annually in funding. In exchange for funding and participating in this organization, Defendants receive access to exclusive meetings and the ability to maintain direct contact with researchers and clinicians who are global influencers on the treatment of atopic dermatitis. Despite its explicit designation as a second-line therapy in the FDA-approved

[37] Simpson EL, Bruin-Weller M, Flohr C, et al. When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. J Am Acad Dermatol. 2017;77(4):623-633. doi:10.1016/j.jaad.2017.06.042
[38] Drucker AM, Eyerich K, de Bruin-Weller MS, et al. Use of systemic corticosteroids for atopic dermatitis: International Eczema Council consensus statement. Br J Dermatol. 2018;178(3):768-775. doi:10.1111/bjd.15928
[39] Drucker AM, Lam M, Flohr C, et al. Systemic Therapy for Atopic Dermatitis in Older Adults and Adults With Comorbidities: A Scoping Review and International Eczema Council Survey. Dermatitis. 2022;33(3):200-206. doi:10.1097/DER.0000000000000845

prescribing information, the current American Academy of Dermatology guidelines for the management of atopic dermatitis strongly recommend Defendants' drug Dupixent as first-line therapy for atopic dermatitis.[40]

87. Defendants similarly sponsor, fund and/or partner with multiple influential organizations that shape guidelines for the prescription of medications in the treatment of other health conditions for which Dupixent has received FDA approval, including the American College of Allergy, Asthma and Immunology, the American Academy of Allergy, Asthma and Immunology, the Allergy & Asthma Network, the American Lung Association, and the American College of Gastroenterology, among many others.

88. Defendants have also gratuitously paid Key Opinion Leaders (KOLs), distinguished researchers and clinicians with strong regional, national and international influence on treatment and prescription practices, to engage in marketing activities, publish research that is favorable to Dupixent and persuade fellow clinicians to prescribe Dupixent to patients with atopic dermatitis, asthma and other inflammatory health conditions.

89. According to United States Centers for Medicare & Medicaid Services (CMS) OpenPayments data, between 2019 and 2024 Defendant Regeneron made 3,643 individual payments to physicians in the United States totaling $3,041,084 for consulting fees, food and beverage costs, education costs and travel and lodging expenses associated with Dupixent. Between 2019 and 2024, Defendant Regeneron's subsidiary, Regeneron Healthcare Solutions, Inc., made 420,649 individual payments to physicians in the United States totaling $45,377,957 for consulting fees, food and beverage costs, education costs and travel and lodging expenses

[40] Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102

associated with Dupixent. Between 2019 and 2024, Defendant Sanofi-Aventis made 14,384 individual payments to physicians in the United States totaling $3,900,992 for consulting fees, food and beverage costs, education costs and travel and lodging expenses associated with Dupixent. Between 2019 and 2024, Sanofi's subsidiary Sanofi US Services Inc. made 249 individual payments to physicians in the United States totaling $325,906 for consulting fees, food and beverage costs, education costs and travel and lodging expenses associated with Dupixent. Finally, between 2019 and 2024, Genzyme Corporation, a wholly-owned subsidiary of Defendant Sanofi-Aventis, made 236,981 individual payments to physicians in the United States totaling $53,277,547 for consulting fees, food and beverage costs, education costs and travel and lodging expenses associated with Dupixent.

90. Collectively, Defendants and their affiliates made 675,906 individual payments to physicians in the United States totaling $105,923,486 for consulting fees, food and beverage costs, education costs and travel and lodging expenses associated with Dupixent between 2019 and 2024.

91. The 2017 "Multidisciplinary Consensus" publication described *supra*[41] provides an excellent example of how Defendants have used direct payments to KOLs to contaminate the practice of medicine for their financial gain. Ten of the 11 authors of this treatment guideline article were retained by Defendants as physician KOLs. In the competing interests section, Defendants disclaim any influence on the development of the treatment recommendations or the manuscript itself, and further aver "No payments were made to the authors for the writing of this manuscript". Despite attempting to manufacture a perception that the recommendations and manuscript were free from bias, Defendants indeed financially enriched each of the authors for

[41] Boguniewicz M, Alexis AF, Beck LA, et al. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. J Allergy Clin Immunol Pract. 2017;5(6):1519-1531. doi:10.1016/j.jaip.2017.08.005

their work directly or indirectly associated with this manuscript. According to data from CMS OpenPayments, in 2017 Defendants paid the physician KOL authors of this manuscript a total of $919,595 for consulting fees, food and beverage costs, education costs and travel and lodging expenses. A breakdown of these payments by author is as follows: Mark Boguniewicz, MD: $240,959; Andrew F. Alexis, MD, MPH: $2,102; Lisa A. Beck, MD: $25,876; Lawrence F. Eichenfield, MD: $100,950; Luz Fonacier, MD: $77,589; Emma Guttman-Yassky, MD, PhD: $91,538; Amy S. Paller, MD: $26,556; David Pariser, MD: $34,375; Jonathan I. Silverberg, MD, PhD, MPH: $316,962; and Mark Lebwohl, MD: $2,688. Furthermore, Defendants' KOL William W. Busse, MD, author of the editorial[42] accompanying the "Multidisciplinary Consensus" article, was paid $57,906 by Defendants in 2017.

92. Defendants also used KOLs to disseminate recommendations to help facilitate the transition of patients from prior effective treatments onto Dupixent, to include patient groups in which Defendants had not studied the safety and efficacy of Dupixent.[43]

93. Further, KOLs played a pivotal role in helping Defendants push for widespread off-label use of Dupixent in the treatment of numerous unapproved inflammatory conditions including, but not limited to chronic pruritus, eczematous eruption of aging, allergic contact dermatitis, chronic hand eczema, alopecia areata, eosinophilic annular erythema and papuloerythroderma of Ofuji.[44]

94. In addition to paying KOLs to promote and increase prescribing of Dupixent,

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[42] Busse WW. Are Biotherapeutics Revolutionizing Treatment of "Allergic" Diseases?. J Allergy Clin Immunol Pract. 2017;5(6):1517-1518. doi:10.1016/j.jaip.2017.08.017

[43] Papp KA, Hong CH, Lansang MP, et al. Practical Management of Patients with Atopic Dermatitis on Dupilumab. Dermatol Ther (Heidelb). 2021;11(5):1805-1828. doi:10.1007/s13555-021-00586-w

[44] Hendricks AJ, Yosipovitch G, Shi VY. Dupilumab use in dermatologic conditions beyond atopic dermatitis - a systematic review. J Dermatolog Treat. 2021;32(1):19-28. doi:10.1080/09546634.2019.1689227

Defendants have also disingenuously leveraged the power of their retained KOLs to sow doubt into any research shedding light on adverse effects that might lead to a reduction in prescriptions of Dupixent as further described *infra*.

95. Defendants' aggressive tactics have paid off. In its first partial year on the market, Dupixent generated $253.8 million in sales in the United States. In 2018, Dupixent sales in the United States climbed to $776.3 million. Dupixent officially became a domestic blockbuster drug in 2019 based on annual sales of $1.87 billion. United States sales of Dupixent continued to increase year over year thereafter, reaching $3.23 billion in 2020, $4.71 billion in 2021, $6.67 billion in 2022, $8.86 billion in 2023 and $10.40 billion in 2024. To date, United States Dupixent sales have exceeded $30 billion.

96. Based on publicly available figures supplied by Defendants, more than an estimated 1 million patients worldwide have been treated with Dupixent across all approved indications.[45]

97. Defendants' surreptitious marketing practices also caught the attention of the United States Department of Justice.[46] In September 2019, Defendant Regeneron and Regeneron Healthcare Services, Inc. each received a civil investigative demand from the Department of Justice pursuant to the federal False Claims Act relating to remuneration paid to physicians in the form of consulting fees, advisory boards, speaker fees and payment or reimbursement for travel and entertainment alleged to be in violation of the federal Anti-Kickback Statute in association with several drugs including Dupixent.

E. Cutaneous T-Cell Lymphoma

98. The instant matter involves injuries of cutaneous T-cell lymphoma (CTCL)

[45] *Atopic Dermatitis*, DUPIXENT, https://www.dupixenthcp.com/atopicdermatitis/ (last visited Dec. 9, 2025).
[46] Annual Report 2024. Regeneron Pharmaceuticals, Inc. https://investor.regeneron.com/pdf/2024AR

associated with the administration of Dupixent.

99. CTCL is a form of non-Hodgkin lymphoma that is initiated by the malignant proliferation of T-cell lymphocytes contained in the skin. CTCL is an extremely rare condition estimated to affect fewer than 10 out of every 1 million people in the United States annually. The disease typically presents with patches, plaques or rashes on the skin and may evolve over years.

100. CTCL is a chronic condition that is generally considered incurable, and accordingly, treatment generally aims to put the disease into remission, leaving the patient with fewer signs and symptoms. Many patients will require several different types of treatments throughout their lifetime. As lesions become more resistant to treatment, or in patients initially presenting with more severe forms of CTCL, more aggressive treatment approaches are usually necessary.

101. CTCL can cause severe itching, pain and physical disfigurement which can significantly impair health-related quality of life, especially in later stages of the disease. CTCL can also metastasize to affect tissues and organs other than the skin. Survival rates vary depending on stage at the time of diagnosis, and patients with moderate to advanced CTCL experience markedly reduced survival.

102. Diagnosis of CTCL is typically made through repeated skin biopsies and blood tests. Imaging and biopsies of lymph nodes and bone marrow may also be performed in certain circumstances. CTCL is graded or staged according to the TNMB (Tumor, Node, Metastasis, Blood) criteria developed by the International Society for Cutaneous Lymphomas and the European Organisation for Research and Treatment of Cancer based the proportion of skin affected by lesions, the type and size of lesions, metastasis to lymph nodes or other organs and the number of Sézary cells in the blood. CTCL stages range from I to IV, and include substages indicated by letters A or B, with higher numbers and letters indicating greater severity.

103. The most common subtypes of CTCL are mycosis fungoides and Sézary syndrome. Other forms of CTCL include peripheral T-cell lymphoma, subcutaneous panniculitis-like T-cell lymphoma, primary cutaneous anaplastic large cell lymphoma and extranodal natural killer/T-cell lymphoma. CTCL and its subtypes fall within a broader category of malignant disease processes referred to as mature T-cell and NK-cell lymphomas.

104. CTCL is typically a non-aggressive and slowly progressing disease, taking an average of 3 to 5 years, and up to 70 years, from initial presentation of symptoms until becoming diagnosable through clinical and histopathological evaluation. Accordingly, patients who have unidentified, subclinical CTCL that goes undiagnosed or is potentially diagnosed as some other dermatosis in the interim are likely to remain asymptomatic and live without clinical or pathological signs of CTCL for long periods of time, or even indefinitely.[47,48,49]

105. CTCL is usually stable, and capable of remaining stable for years. However, certain environmental triggers can prompt rapid disease progression. Indeed, when undiagnosed or misdiagnosed as another dermatosis, treatment-emergent "unmasking" of CTCL has long been a known risk with the use of certain medications.[50]

106. Atopic dermatitis has been a well-known and widely documented health condition, often classified under the name eczema, among the medical community since at least the

[47] Kim YH, Liu HL, Mraz-Gernhard S, Varghese A, Hoppe RT. Long-term outcome of 525 patients with mycosis fungoides and Sezary syndrome: clinical prognostic factors and risk for disease progression. Arch Dermatol. 2003;139(7):857-866. doi:10.1001/archderm.139.7.857
[48] Lavin L, Geller S. Cutaneous T Cell Lymphoma Following Dupilumab Therapy in Patients with Atopic Dermatitis: Clinical Review and Recommendations. Am J Clin Dermatol. 2025;26(5):723-731. doi:10.1007/s40257-025-00955-7
[49] Hristov AC, Tejasvi T, Wilcox RA. Cutaneous T-cell lymphomas: 2023 update on diagnosis, risk-stratification, and management. Am J Hematol. 2023;98(1):193-209. doi:10.1002/ajh.26760
[50] Foo SH, Shah F, Chaganti S, Stevens A, Scarisbrick JJ. Unmasking mycosis fungoides/Sézary syndrome from preceding or co-existing benign inflammatory dermatoses requiring systemic therapies: patients frequently present with advanced disease and have an aggressive clinical course. Br J Dermatol. 2016;174(4):901-904. doi:10.1111/bjd.14238

1800s.[51,52] Early studies observed no association between atopic dermatitis and CTCL, alternatively finding that rates of atopic dermatitis were very low in CTCL patients and not significantly different from the general population.[53,54] The sequential observation of atopic dermatitis followed by mycosis fungoides or Sézary syndrome was also extremely rare.[55,56] However, as the use of powerful immunomodulating therapies in the treatment of dermatological conditions became commonplace, reports of CTCL in patients with atopic dermatitis – including both new-onset cases and rapid progression of pre-malignant cases – began to appear more frequently in the literature. Unsurprisingly, the ensuing expanded utilization of biological therapeutics in the management of dermatologic conditions was accompanied by a parallel rise in CTCL diagnoses in treated patients.[57,58,59,60] At the same time, studies reporting an increased risk of CTCL attributable to atopic dermatitis – as opposed to atopic dermatitis medications – have almost exclusively been funded and conducted by manufacturers of atopic dermatitis medications

[51] Crawford A. Case of Eczema Rubrum, with Remarks. Edinb Med Surg J. 1820;16(62):37-41.
[52] Green J. Dr. Green's Observations on the Treatment of Eczema. Med Exam (Phila). 1842;5(40):637-640.
[53] Tuyp E, Burgoyne A, Aitchison T, MacKie R. A case-control study of possible causative factors in mycosis fungoides. Arch Dermatol. 1987;123(2):196-200.
[54] Mehrany K, El-Azhary RA, Bouwhuis SA, Pittelkow MR. Cutaneous T-cell lymphoma and atopy: is there an association?. Br J Dermatol. 2003;149(5):1013-1017. doi:10.1111/j.1365-2133.2003.05551.x
[55] Rajka G, Winkelmann RK. Atopic dermatitis and Sézary syndrome. Arch Dermatol. 1984;120(1):83-84.
[56] Lange-Vejlsgaard G, Ralfkiaer E, Larsen JK, O'Connor N, Thomsen K. Fatal cutaneous T cell lymphoma in a child with atopic dermatitis. J Am Acad Dermatol. 1989;20(5 Pt 2):954-958. doi:10.1016/s0190-9622(89)70118-3
[57] Sokołowska-Wojdyło M, Barańska-Rybak W, Cegielska A, Trzeciak M, Lugowska-Umer H, Gniadecki R. Atopic dermatitis-like pre-Sézary syndrome: role of immunosuppression. Acta Derm Venereol. 2011;91(5):574-577. doi:10.2340/00015555-1149
[58] Dequidt L, Franck N, Sanchez-Pena P, et al. Cutaneous lymphomas appearing during treatment with biologics: 44 cases from the French Study Group on Cutaneous Lymphomas and French Pharmacovigilance Database. Br J Dermatol. 2019;181(3):616-618. doi:10.1111/bjd.17834
[59] Amitay-Laish I, Guenova E, Ortiz-Romero PL, et al. The Course of Mycosis Fungoides under Cytokine Pathway Blockers: A Multicentre Analysis of Real-life Clinical Data. Acta Derm Venereol. 2020;100(16):adv00277. Published 2020 Sep 30. doi:10.2340/00015555-3642
[60] Davis MS, Spencer RK, Johnson CE, et al. Risk of Cutaneous T Cell Lymphoma with Psoriasis Biologic Therapies. Dermatol Ther (Heidelb). 2024;14(1):15-30. doi:10.1007/s13555-023-01074-z

and their associates.[61,62,63,64,65]

F. Dupixent and CTCL

107. Despite its historical infrequence in the population, CTCL has been widely reported among patients taking Dupixent. These cases have included diagnoses of new, primary CTCL as well as severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL occurring weeks to years following initiation of Dupixent use.

a. Clinical Trials

108. Years before its approval for marketing by FDA, CTCL was first reported in a patient treated with Dupixent in a Phase II clinical trial in adults with atopic dermatitis (Study R668-AD-1314). In this study, mycosis fungoides stage IV was reported in 1 of 97 (1.03%) subjects treated with dupilumab and 0 of 97 subjects assigned to placebo.[66] According to the FDA Medical Review for Dupixent, this subject presented on day 35 of treatment with apparent worsening of his atopic dermatitis after receiving 7 doses of Dupixent 300 mg. After receiving another dose on day 43, his atopic dermatitis was considered "completely refractory to treatment", and skin biopsies were obtained. On day 48 this subject was formally diagnosed with mycosis

[61] Arellano FM, Wentworth CE, Arana A, Fernández C, Paul CF. Risk of lymphoma following exposure to calcineurin inhibitors and topical steroids in patients with atopic dermatitis. J Invest Dermatol. 2007;127(4):808-816. doi:10.1038/sj.jid.5700622

[62] Legendre L, Barnetche T, Mazereeuw-Hautier J, Meyer N, Murrell D, Paul C. Risk of lymphoma in patients with atopic dermatitis and the role of topical treatment: A systematic review and meta-analysis. J Am Acad Dermatol. 2015;72(6):992-1002. doi:10.1016/j.jaad.2015.02.1116

[63] Wan J, Shin DB, Syed MN, et al. Malignancy risk in patients with atopic dermatitis: a population-based cohort study. Br J Dermatol. 2023;189(1):53-61. doi:10.1093/bjd/ljad072

[64] Powers CM, Piontkowski AJ, Orloff J, et al. Risk of lymphoma in patients with atopic dermatitis: A case-control study in the All of Us database. J Am Acad Dermatol. 2024;91(2):344-346. doi:10.1016/j.jaad.2024.03.038

[65] Ma Y, Chachin M, Hirose T, et al. Prevalence and incidence of comorbidities in patients with atopic dermatitis, psoriasis, alopecia areata, and vitiligo using a Japanese claims database. J Dermatol. 2025;52(5):841-854. doi:10.1111/1346-8138.17643

[66] Center for Drug Evaluation and Research. Medical Review: Dupixent (dupilumab). Application Number 761055. U.S. Food and Drug Administration. March 2017.

fungoides stage IV and Dupixent was discontinued. Mycosis fungoides stage IV was noted to be ongoing at the end of the study.[67]

109. Following this and another CTCL clinical trial case, Defendants amended the study protocol for the ongoing Phase III open-label trial (R668-AD-1225) on January 12, 2015, to designate "mycosis fungoides and cutaneous T-cell dyscrasias" as adverse events of special interest (AESIs).[68]

110. The results of the Phase III open-label extension trial were eventually posted to ClinicalTrials.gov in October 2023 and published in JAMA Dermatology in July 2024 and indicated CTCL was reported in a total of 3 patients who continued their Dupixent treatment from prior clinical trials. One additional subject treated with Dupixent developed T-cell lymphoma.[69] Mycosis fungoides was noted to be one of the 5 most common treatment-emergent adverse events leading to discontinuation.[70]

111. Importantly, randomized controlled trials suffer from several important limitations

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[67] Blauvelt A, Simpson EL, Tyring SK, et al. Dupilumab does not affect correlates of vaccine-induced immunity: A randomized, placebo-controlled trial in adults with moderate-to-severe atopic dermatitis. J Am Acad Dermatol. 2019;80(1):158-167.e1. doi:10.1016/j.jaad.2018.07.048

[68] Defendants downplayed the risk of CTCL when communicating with the FDA prior to receiving drug approval. For example, Defendants designated mycosis fongoides and cutaneous T-cell dyscrasias as "adverse events of special interest" because "they may be misdiagnosed as chronic AD." Clinical Review, Brenda Carr, MD, at 166, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761055Orig1s000MedR.pdf; *See also* 11/14/14 CDER Medical Policy Council, Breakthrough Therapy Designation Requests at 1-2 at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761055Orig1s000OtherR.pdf ("The adverse event of concern with dupilumab is cutaneous T-cell lymphoma (CTCL) reported in one patient on therapy in trial #1225, open label long term. Lymphoma is difficult to diagnosis in these patients. DDDP also noted that CTCL was seen in a placebo patient in the another [sic] trial, 1026, phase 2 sequential ascending dose trial. This patient may have had CTCL when entering the trial. For the patient on study drug, the event seen may regress once the patient is off study drug.").

[69] U.S. National Library of Medicine. NCT01949311. Open-label Study of Dupilumab in Patients With Atopic Dermatitis. https://clinicaltrials.gov/study/NCT01949311

[70] Beck LA, Bissonnette R, Deleuran M, et al. Dupilumab in Adults With Moderate to Severe Atopic Dermatitis: A 5-Year Open-Label Extension Study. JAMA Dermatol. 2024;160(8):805-812. doi:10.1001/jamadermatol.2024.1536

that restrict the generalizability of their results to real-world populations, and many patients exposed to a drug after its approval have disease features and comorbidities or use concomitant medications which would have rendered them ineligible to participate in premarket clinical trials. This limitation is particularly true for safety endpoints, as premarket clinical trials are typically too small in size and too short in duration to detect rare, serious adverse events that may be associated with the treatment. This is because premarket clinical trials are primarily designed to detect differences between groups in efficacy endpoints, with safety being a secondary consideration. The Dupixent pivotal trials were no exception.

112. Across the 3 Dupixent pivotal trials in the treatment of atopic dermatitis, 1,344 patients were randomized to Dupixent, with just 563 following the dosing schedule that was ultimately approved by the FDA. Subjects in 2 of the pivotal trials were only treated with Dupixent for up to 16 weeks, and in the third pivotal trial subjects were treated with Dupixent for up to 52 weeks. Defendants' clinical development safety database for atopic dermatitis included a total of 2,526 subjects who received at least 1 dose of Dupixent. Notably, however, while Dupixent is intended to be a chronic therapy for indefinite use, the Defendants' clinical development safety database included just 160 subjects with at least 2 years of exposure to any dose of Dupixent at the time they submitted their BLA seeking an indication in atopic dermatitis.[71]

113. The safety populations in Defendants' subsequent clinical development programs for Dupixent in the treatment of other conditions were even smaller or exposed to Dupixent for shorter durations than the atopic dermatitis development program. Defendants' clinical development safety database for asthma in patients 12 years of age and older included 1,670 subjects who received at least one dose of Dupixent at the time of BLA submission. Among these,

[71] Center for Drug Evaluation and Research. Medical Reviews: Dupixent (dupilumab). Application Number 761055. U.S. Food and Drug Administration. March 2017.

only 350 were treated with Dupixent for at least 1 year, and no subjects were treated for 2 or more years.[72] The safety database for atopic dermatitis in 12 to 17-year-olds included just 322 subjects treated with at least 1 dose of Dupixent, of which only 35 received at least 1 year of treatment and 27 received 2 years of treatment at the time of BLA submission.[73] The chronic rhinosinusitis with nasal polyps clinical development safety database included only 440 subjects treated with at least 1 dose of Dupixent at the time of BLA submission, with 83 being treated for at least 1 year and none being treated for 2 or more years.[74] Finally, Defendants' eosinophilic esophagitis safety database included only 367 subjects who received at least 1 dose of Dupixent at the time of BLA submission. Of 182 patients who received the recommended Dupixent dosage regimen, 40 were treated for at least 1 year and none were treated for 2 or more years.[75]

114. Given the small number of exposed patients and short periods of treatment and observation in the Dupixent clinical development programs, it is not surprising that rare and serious treatment-emergent safety concerns would begin to emerge with long-term use among hundreds of thousands of patients during the postmarketing period. This phenomenon was all the more likely given that, thanks to Defendants' successful marketing scheme, the patients being treated with Dupixent in the real world were far more diverse than the populations that were enrolled in premarket clinical trials.[76]

115. Indeed, following its approval for marketing in the United States in March 2017,

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[72] Center for Drug Evaluation and Research. Approval Package: Dupixent (dupilumab). Application Number 761055Orig1s007. U.S. Food and Drug Administration. October 2018.
[73] Center for Drug Evaluation and Research. Approval Package: Dupixent (dupilumab). Application Number 761055Orig1s012. U.S. Food and Drug Administration. March 2019.
[74] Center for Drug Evaluation and Research. Approval Package: Dupixent (dupilumab). Application Number 761055Orig1s014. U.S. Food and Drug Administration. June 2019.
[75] Center for Drug Evaluation and Research. Approval Package: Dupixent (dupilumab). Application Number 761055Orig1s040. U.S. Food and Drug Administration. May 2022.
[76] Papp KA, Hong CH, Lansang MP, et al. Practical Management of Patients with Atopic Dermatitis on Dupilumab. Dermatol Ther (Heidelb). 2021;11(5):1805-1828. doi:10.1007/s13555-021-00586-w

multiple independent clinicians and researchers began investigating and reporting a concerning association between Dupixent use and the development of CTCL. This large and growing body of research has been published in the form of cohort studies, cross-sectional studies, analyses of postmarketing adverse events, systematic reviews, case series and individual case reports.

b. Case Reports, Case Series and Descriptive Observational Studies

116. On November 30, 2018, a published abstract described a 49-year-old female with a history of atopic dermatitis who experienced worsening of her disease over the preceding 6 years.[77] Following an inadequate response to treatment with cyclosporine and methotrexate, the patient was started on Dupixent. After 3 months of Dupixent treatment, she developed right inguinal lymph node enlargement, plaques on her neck, elbow and lower back, and a rapidly ulcerated lesion under her right nipple. Biopsy revealed CD30+ ALK1-negative cutaneous anaplastic large cell lymphoma and positron emission tomography confirmed right inguinal, cervical and right external iliac lymph node involvement. The authors noted that anaplastic large cell lymphoma was not known to be associated with atopic dermatitis, and that prior research had shown Th2 pathway involvement in oncogenesis via IL-4 and IL-13.

117. An additional case report was published on May 2, 2019, documenting CTCL in a patient treated with Dupixent.[78] The patient in this case had atopic dermatitis since early childhood, with remission in adolescence and reemergence at age 47. Due to an inadequate response to other treatments and persistent itching, Dupixent was prescribed to treat his atopic dermatitis at age 58. One month of Dupixent treatment failed to alleviate atopic dermatitis symptoms and instead

[77] Bozon A, Dereure O, Szablewski V, Vincent T, Du Thanh A, Gustave V. P268: Lymphome à grandes cellules ALK1 négatif CD 30+ avec atteintes ganglionnaire et cutanée sous dupilumab. Annales de Dermatologie et de Vénéréologie. 2018;145(12):S272-S273. doi:10.1016/j.annder.2018.09.430

[78] Chiba T, Nagai T, Osada SI, Manabe M. Diagnosis of Mycosis Fungoides Following Administration of Dupilumab for Misdiagnosed Atopic Dermatitis. Acta Derm Venereol. 2019;99(9):818-819. doi:10.2340/00015555-3208

induced a flare-up of cutaneous lesions. Based on the results of histopathology and computed tomography scans, the patient was diagnosed with mycosis fungoides and Dupixent was discontinued. Despite a long history of atopic dermatitis, these authors proposed that this patient may have had mycosis fungoides that was misdiagnosed as atopic dermatitis.

118. On September 24, 2019, a case of mycosis fungoides in a patient treated with Dupixent for atopic eczema was presented at the 2019 Cutaneous Lymphoma Task Force Meeting of the European Organisation for Research and Treatment of Cancer (EORTC).[79] This subject developed widespread rash and lymphadenopathy 9 weeks after initiating Dupixent. Dupixent was discontinued, and after initial improvement, the subject experienced rapid disease progression and was diagnosed with mycosis fungoides. Based on their assessment, the authors believed this patient may have had preexisting mycosis fungoides which rapidly progressed upon starting treatment with Dupixent.

119. Also at the September 2019 Cutaneous Lymphoma Task Force Meeting of the EORTC, researchers from several universities presented the results of a descriptive study investigating CTCL among patients treated with biologics; this study was formally published in September 2020.[80] These researchers included all patients diagnosed with mycosis fungoides while being treated with tumor necrosis factor-alpha inhibitors, IL-17 inhibitors, IL-12/23 inhibitors or IL-23 inhibitors and managed at multiple Cutaneous Lymphoma Clinics through June 2019. Among 19 included patients, the authors incidentally identified 2 patients who had been treated with Dupixent – in addition to other biologics meeting study inclusion criteria – for a presumed

[79] Poyner E, Bacon C, Meggitt S, Weatherhead S. A case of mycosis fungoides with large cell transformation following dupilumab treatment. Eur J Cancer. 2019;119:S42–S43

[80] Amitay-Laish I, Guenova E, Ortiz-Romero PL, et al. The Course of Mycosis Fungoides under Cytokine Pathway Blockers: A Multicentre Analysis of Real-life Clinical Data. Acta Derm Venereol. 2020;100(16):adv00277. Published 2020 Sep 30. doi:10.2340/00015555-3642

atopic dermatitis or psoriasis. These patients were retrospectively diagnosed as having preexisting mycosis fungoides, and both experienced disease progression during treatment with Dupixent and other biologics. In one patient patches progressed to plaques and in the other stage III mycosis fungoides progressed to stage IV mycosis fungoides with blood involvement. The authors cautioned "before considering biologics for benign cutaneous inflammatory disorders, clinicians should re-think the indication, take a second look for clinical clues of MF, revise the histology or take another biopsy, and consider blood assessment, including flow cytometry".

120. A third abstract from the September 2019 Cutaneous Lymphoma Task Force Meeting of the EORTC described a series of patients with newly diagnosed mycosis fungoides after initiating biologic medications for atopic dermatitis or psoriasis.[81] One patient, a 44-year-old female who had a life-long history of atopic dermatitis, started using Dupixent in April 2018 and initially responded to the therapy. However, after 10 months of Dupixent treatment, her condition worsened, at which point a biopsy revealed Stage II mycosis fungoides. These authors advised that patients should undergo screening with biopsies before starting treatment with biologics.

121. On March 27, 2020, clinicians published a case series of 4 patients with atopic dermatitis and 3 patients with preexisting CTCL treated with Dupixent.[82] After a brief initial improvement on Dupixent, both groups of patients experienced worsening of their symptoms. The 4 atopic dermatitis patients began to develop palmoplantar desquamation, severe skin burning and pruritus, erythroderma, and enlargement and thickening of plaques, and were eventually diagnosed

[81] Yoo J, Shah F, Velangi S, Stewart G, Hague J, Scarisbrick J. Three cases of new diagnosis of mycosis fungoides following commencement on biologic therapies for presumed psoriasis/eczema. Eur J Cancer. 2019;119:S41

[82] Espinosa ML, Nguyen MT, Aguirre AS, et al. Progression of cutaneous T-cell lymphoma after dupilumab: Case review of 7 patients. J Am Acad Dermatol. 2020;83(1):197-199. doi:10.1016/j.jaad.2020.03.050. An abstract of this study was also published in April 2020. Espinosa ML, Nguyen MT, Aguirre AS, et al. P44: Dupilumab is associated with disease worsening or unmasking of cutaneous T-cell lymphoma. Br J Dermatol. 2020;183(4):25. doi:10.1111/bjd.19043

with mycosis fungoides or CTCL (not otherwise specified) after 4 to 27 months of Dupixent treatment. Additionally, 2 of the 3 patients with preexisting CTCL being treated with Dupixent progressed from mycosis fungoides to Sézary syndrome stage IV and ultimately died due to CTCL progression. After presenting the details of these cases, these authors noted "our observations highlight the need for caution when using dupilumab in patients with atypical dermatitis presentations without previous exclusion of Cutaneous T-cell lymphoma via skin biopsy, testing for T-cell receptor gene rearrangement, and flow cytometry of the blood", and further advised "[a]s dupilumab becomes more commonplace in the treatment of atopic dermatitis and atopic disease, we anticipate seeing a greater number of cases of unmasked Cutaneous T-cell lymphoma in patients who initially received a diagnosis of atypical atopic dermatitis".

122. In April 2020, physicians published another case report of an atopic dermatitis patient who developed CTCL while being treated with Dupixent.[83] Just 2 weeks after receiving his first 600 mg loading dose of Dupixent, this patient presented with an erythrodermic rash covering 95% of his body surface. Additional treatments were initiated to control the erythroderma and newly diagnosed psoriasis, but erythroderma and lymphadenopathy persisted and prompted further testing. After 3 months of Dupixent treatment, this patient was diagnosed with Sézary syndrome. The authors concluded "The temporal relationship between the initiation of dupilumab and the onset of erythroderma suggests that dupilumab was a trigger for [Sézary syndrome] in this patient" and advised "clinicians should be aware of this association for prompt diagnosis and treatment". These authors further cautioned "Although dupilumab provides promise in the treatment of atopic and allergic conditions, clinicians should take into account its novelty and the potential for unexpected adverse events".

[83] Tran J, Morris L, Vu A, Duvic M. Development of Sézary syndrome following the administration of dupilumab. Dermatol Online J. 2020;26(4):13030/qt1m67z8sb. Published 2020 Apr 15.

123. On June 18, 2020, another case series involving Dupixent and CTCL was published reporting on the clinical courses of 1 patient with atopic dermatitis and another patient with mycosis fungoides and a history of atopic dermatitis who were both treated with Dupixent.[84] While the patient with mycosis fungoides and atopic dermatitis experienced improvement in his symptoms after starting Dupixent, the atopic dermatitis-only patient failed to respond to Dupixent treatment over a 2-month period. This patient instead developed intense pruritus, skin plaques and palmoplantar keratosis and was ultimately diagnosed with Sézary syndrome.

124. In another case report published June 19, 2020, Dupixent was initiated in a patient with a 1-year history of atopic dermatitis.[85] Following 8 doses of Dupixent, the patient experienced worsening lesions, spreading plaques and the appearance of new ulcerated tumors, and was ultimately diagnosed with tumoral-stage mycosis fungoides.

125. On July 16, 2020, another case report involving CTCL in the setting of Dupixent use was published.[86] This patient had a history of atopic dermatitis since infancy which had worsened over the previous 2 years. After administering 3 doses of Dupixent, the patient presented with severe exfoliative erythroderma with superficial lymph node swelling. Following a battery of tests, the patient was diagnosed with Sézary syndrome.

126. A case series was published on August 27, 2020 describing CTCL in 3 Dupixent-

[84] Lazaridou I, Ram-Wolff C, Bouaziz JD, et al. Dupilumab Treatment in Two Patients with Cutaneous T-cell Lymphomas. Acta Derm Venereol. 2020;100(16):adv00271. Published 2020 Sep 30. doi:10.2340/00015555-3576

[85] Miyashiro D, Vivarelli AG, Gonçalves F, Cury-Martins J, Sanches JA. Progression of mycosis fungoides after treatment with dupilumab: A case report. Dermatol Ther. 2020;33(6):e13880. doi:10.1111/dth.13880

[86] Umemoto N, Demitsu T, Otaki K, et al. Dupilumab therapy in Sézary syndrome misdiagnosed as atopic dermatitis: A case report. J Dermatol. 2020;47(10):e356-e357. doi:10.1111/1346-8138.15501

treated patients with long-standing histories of adult-onset dermatitis.[87] After receiving 6 or fewer injections of Dupixent, each of these patients experienced an acute exacerbation of their dermatitis. Upon discontinuation of Dupixent, each patient was diagnosed with mycosis fungoides.

127. On December 16, 2020, another case report of CTCL developing in a patient with atopic dermatitis treated with Dupixent was published.[88] Despite initial limited improvement of his symptoms, two months after initiating Dupixent the patient presented with significant worsening of his dermatitis, weight loss and marked lymphadenopathy, and was diagnosed with mycosis fungoides stage IV. In their discussion, the authors advocated for diligent monitoring of disease course after Dupixent initiation and prompt evaluations for CTCL in patients that exhibit an inadequate response to treatment.

128. In December 2020, a case report describing a case of CTCL involving Dupixent in a 40-year-old female with a history of atopic dermatitis since childhood was published.[89] Following initial improvement, this patient exhibited a flare of her atopic dermatitis symptoms after 5 months of taking Dupixent. She continued Dupixent treatment for another 8 months, during which she experienced widespread progression of lesions to 80% of her body surface area. This patient discontinued Dupixent and was ultimately diagnosed with mycosis fungoides stage II.

129. In January 2021, a case series of 2 patients developing CTCL shortly after starting treatment with Dupixent was published.[90] Both patients were treated with Dupixent for atopic

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[87] Hollins LC, Wirth P, Fulchiero GJ Jr, Foulke GT. Long-standing dermatitis treated with dupilumab with subsequent progression to cutaneous T-cell lymphoma. Cutis. 2020;106(2):E8-E11. doi:10.12788/cutis.0074

[88] Russomanno K, Carver DeKlotz CM. Acceleration of cutaneous T-cell lymphoma following dupilumab administration. JAAD Case Rep. 2020;8:83-85. Published 2020 Dec 17. doi:10.1016/j.jdcr.2020.12.010

[89] Ayasse M, Nelson K, Glass F, Silverberg JI. Mycosis Fungoides Unmasked by Dupilumab Treatment in a Patient With a History of Atopic Dermatitis. Dermatitis. 2021;32(1S):e88-e89. doi:10.1097/DER.0000000000000679

[90] Newsom M, Hrin ML, Hamid RN, et al. Two cases of mycosis fungoides diagnosed after treatment non-response to dupilumab. Dermatol Online J. 2021;27(1):13030/qt1133121d. Published 2021 Jan 15.

dermatitis for approximately 5 months. After failing to respond to treatment, biopsies were ordered revealing mycosis fungoides. In discussing the cases, these authors found their report to "highlight[ed] the importance of considering cutaneous lymphoma when treating inflammatory dermatoses that are recalcitrant to targeted immunotherapies".

130. On April 22, 2021, a German clinician published a case report involving a patient who developed mycosis fungoides large-cell anaplastic T-cell lymphoma with involvement of the supraclavicular lymph node after initiating treatment with Dupixent.[91]

131. On October 11, 2021, a case report of CTCL with a fatal outcome following initiation of Dupixent was published in JAAD Case Reports.[92] The patient experienced an improvement in skin inflammatory lesions after 5 months of Dupixent treatment, but again presented to her physician 3 weeks after developing new painful, erythematous and ulcerated plaques on her breast. Testing revealed features suggestive of an anaplastic large-cell lymphoma with cutaneous and systemic involvement and Dupixent was immediately discontinued. During the following month, the patient rapidly developed a similar skin tumor on her left forearm and rapidly progressive inguinal lymph nodes. Despite achieving a partial response after 2 lines of systemic chemotherapies, the patient ultimately died of pulmonary cytomegalovirus infection associated with severe hypoxemic infiltrative fibrosis just 12 months following the onset of the first lesion on her breast. The authors considered this unfortunate case as "add[ing] to the literature of new-onset cutaneous lymphomas associated with dupilumab therapy".

132. In October 2021, researchers from Mayo Clinic published a study of histopathologic

[91] Troyanova-Slavkova S. Großzellig-anaplastisches T-Zell-Lymphom und mycosis fungoides unter der Therapie mit Dupilumab [Anaplastic Large-Cell T-Cell Lymphoma and mycosis fungoides under Therapy with Dupilumab]. Aktuelle Dermatologie 2021;47(07):331-334. doi:10.1055/a-1402-9645
[92] Du-Thanh A, Gustave V, Dereure O. Lethal anaplastic large-cell lymphoma occurring in a patient treated with dupilumab. JAAD Case Rep. 2021;18:4-7. Published 2021 Oct 12. doi:10.1016/j.jdcr.2021.09.020

features in 7 atopic dermatitis patients who developed atypical lymphoid infiltrate or mycosis fungoides while taking Dupixent.[93] All 7 patients had biopsy-proven atopic dermatitis (average of 3.4 pre-treatment biopsies), reconfirmed through secondary histopathologic review at the time of the study, and none had CTCL before starting Dupixent. These patients were between 27 and 74 years of age with an average length of Dupixent treatment of 9.8 months before developing CTCL. After starting Dupixent, all 7 patients demonstrated progressive increases in the densities of atypical lymphoid infiltrates while 6 had new atypical epidermotropic lymphocytes and papillary dermal fibrosis. One patient experienced progressive worsening of symptoms 12 months post-Dupixent initiation and received a diagnosis of mycosis fungoides stage IV. Despite chemotherapy, this patient developed systemic symptoms and lymphadenopathy, and ultimately died of complications of CTCL 6 months after her diagnosis. Based on their findings, these authors recommended serial biopsies of patients before and during treatment with Dupixent.

133. On December 27, 2021, a case report of CTCL in a 38-year-old patient with atopic dermatitis after starting Dupixent was published.[94] This patient had been treated with topical steroids for 3 years and Dupixent for 1 year when he began developing steroid-resistant disseminated papules. Upon presentation, this patient showed no physical or histopathologic signs of CTCL. Seven months later the patient experienced rapid enlargement of a nodule in his inguinal region that demonstrated lymph node involvement on positron emission tomography and dense infiltration of CD30+ and ALK-lymphocytes on biopsy. He was diagnosed with CD30 + ALK-nodal anaplastic large cell lymphoma and treated with chemotherapy. The authors concluded that

[93] Sokumbi O, Shamim H, Davis MDP, Wetter DA, Newman CC, Comfere N. Evolution of Dupilumab-Associated Cutaneous Atypical Lymphoid Infiltrates. Am J Dermatopathol. 2021;43(10):714-720. doi:10.1097/DAD.0000000000001875

[94] Amagai M, Ozawa M, Amagai R, et al. Nodal anaplastic large cell lymphoma with lymphomatoid papulosis following treatment of initially presumed atopic dermatitis with dupilumab: A case report. Dermatol Ther. 2022;35(3):e15290. doi:10.1111/dth.15290

their case indicated Dupixent could accelerate CD30+ lymphoproliferative disorders.

134. Additional case reports of new CTCL development and rapid CTCL progression in patients after starting Dupixent continued to be published in the succeeding months. Such publications included a case report of peripheral T-cell lymphoma in March 2022,[95] a case report of rapidly progressing and ultimately fatal CTCL in May 2022,[96] an aggressive and fatal case of primary cutaneous gamma-delta T-cell lymphoma in May 2022,[97] a case of erythrodermic mycosis fungoides with suspected blood involvement in August 2022[98] and a case of "dupilumab-associated CD8+ [mycosis fungoides]" stage II in November 2022.[99]

135. In August 2022, researchers from the Mayo Clinic published a descriptive analysis of CTCL among patients treated with biological therapies at their facility.[100] Over the preceding 10-year period, 17 patients treated with biologics for rheumatologic, dermatologic or gastrointestinal conditions had subsequently been diagnosed with CTCL. Among these 17 patients, most (n=9; 53%) had been treated with Dupixent for atopic dermatitis for between 1.2 and 24 months before their CTCL diagnosis. Specific diagnoses included mycosis fungoides, Sézary

[95] Nakazaki K, Yoshida M, Masamoto Y, et al. Discordant lymphomas of classic Hodgkin lymphoma and peripheral T-cell lymphoma following dupilumab treatment for atopic dermatitis. Int J Hematol. 2022;116(3):446-452. doi:10.1007/s12185-022-03330-y

[96] Poyner EFM, Bacon CM, Osborne W, Frew JA, Weatherhead SC. Dupilumab unmasking cutaneous T-cell lymphoma: report of a fatal case. Clin Exp Dermatol. 2022;47(5):974-976. doi:10.1111/ced.15079

[97] Ahatov R, Good AJ, Joo M, Tipton S, Goodwin B, Kelly B. A rare case of aggressive cytotoxic T-cell lymphoma in a patient on dupilumab. JAAD Case Rep. 2022;24:112-114. Published 2022 May 10. doi:10.1016/j.jdcr.2022.04.023

[98] Hashimoto M, Miyagaki T, Komaki R, Takeuchi S, Kadono T. Development of Nodular Lesions after Dupilumab Therapy in Erythrodermic Mycosis Fungoides with Interleukin-13 Receptor alpha2 Expression. Acta Derm Venereol. 2022;102:adv00766. Published 2022 Aug 24. doi:10.2340/actadv.v102.2234

[99] Park A, Wong L, Lang A, Kraus C, Anderson N, Elsensohn A. Dupilumab-Associated Mycosis Fungoides with a CD8+ Immunophenotype. Dermatopathology (Basel). 2022;9(4):385-391. Published 2022 Nov 30. doi:10.3390/dermatopathology9040045

[100] Schaefer L, Comfere NI, Sokumbi O. Development of cutaneous T-cell lymphoma following exposure to biologic therapy: a Mayo Clinic retrospective analysis. Int J Dermatol. 2023;62(7):e371-e374. doi:10.1111/ijd.16386

syndrome and peripheral T-cell lymphoma. One of these subjects had effectively managed her long-standing atopic dermatitis with methotrexate for over 10 years and only switched to Dupixent when she no longer responded to her maintenance treatment. Within 7 months of starting Dupixent she developed peripheral T-cell lymphoma stage IV and died 8 months later. These authors advised "further prospective investigations are warranted to elucidate dupilumab's role in the development of CTCL. This is especially relevant, given its common use in the management of AD and growing clinical indications for use including chronic urticaria, bullous pemphigoid, and alopecia areata."

136. Still more case reports of CTCL development in patients after starting Dupixent treatment continued to be published in 2023 and 2024, including a case of angioimmunoblastic T-cell lymphoma in January 2023,[101] a case of mycosis fungoides in March 2023,[102] a case of peripheral T-cell lymphoma "presumably associated with dupilumab" in April 2023,[103] a case of mycosis fungoides stage III in May 2023,[104] a case of rapidly progressive CD30+ mycosis fungoides in May 2023,[105] a case of Sézary syndrome in July 2023,[106] a case of CTCL in August

[101] Choo ZY, Akinyemi AA, Cibull T, Mehlis S, Waldinger JB. Angioimmunoblastic T-cell lymphoma unmasked by treatment with dupilumab. JAAD Case Rep. 2023;33:87-90. Published 2023 Jan 26. doi:10.1016/j.jdcr.2023.01.008

[102] Yan D, Ramachandran V, Weston G, Kim RH, Latkowski JA. Diagnosing mycosis fungoides after initiation of therapy with dupilumab: a case report and literature review. Int J Dermatol. 2023;62(9):e500-e503. doi:10.1111/ijd.16641

[103] Shimada M, Inano S, Kitano T. T-cell lymphoma associated with dupilumab. Ann Hematol. 2023;102(6):1601-1602. doi:10.1007/s00277-023-05237-y

[104] Hsieh CY, Tsai TF. Rapid progression of cutaneous T-cell lymphoma in a patient with erythroderma during dupilumab treatment, following prior sequential azathioprine, baricitinib and cyclosporine treatments. Indian J Dermatol Venereol Leprol. Published online May 1, 2023. doi:10.25259/IJDVL_1090_2022

[105] Toker M, Srivastava P, Amin B, Wu B. Did dupilumab unmask smoldering mycosis fungoides?. JAAD Case Rep. 2023;38:11-13. Published 2023 May 30. doi:10.1016/j.jdcr.2023.05.025

[106] Hamp A, Hanson J, Alhatem A, Schwartz RA. Dupilumab-Associated Sezary Syndrome. Indian J Dermatol. 2023;68(4):459-462. doi:10.4103/ijd.ijd_580_22

2023[107] and a case of folliculocentric mycosis fungoides in May 2024.[108]

137. Researchers from Mayo Clinic published a systematic review of cases of CTCL reported in patients treated with biological therapies in January 2023.[109] The authors identified 28 studies describing 62 patients who had developed CTCL following exposure to a biologic agent. Among these CTCL cases, Dupixent was the most commonly used biologic agent (42%), despite several others being on the market for longer and with much greater overall patient exposure.

138. In March 2023, researchers from Johns Hopkins University School of Medicine presented the results of a single center retrospective study of patients with CTCL at the Annual Meeting of the American Academy of Dermatology.[110] Researchers identified 411 patients with CTCL, of which 6 were found to have received Dupixent for biopsy-proven atopic dermatitis prior to being diagnosed with mycosis fungoides or Sézary syndrome. Initial diagnosis of atopic dermatitis had been made in adulthood for 5 and in childhood in 1, and 2 patients experienced worsening of their disease after starting Dupixent. The authors concluded "[d]upilumab can be associated with worsening skin disease".

139. In June 2023, researchers from Saint Louis University School of Medicine, Rutgers New Jersey Medical School and Arizona College of Osteopathic Medicine published a cross-sectional study based on 25 patients – 20 cases published in the literature and 5 from their

[107] Malick H, Wilson A, Hall M, Meier M. Cutaneous T-cell Lymphoma Progression: A Potential Dupilumab Pitfall. Cureus. 2023;15(8):e42959. Published 2023 Aug 4. doi:10.7759/cureus.42959
[108] Jiang SY, Yeh J, Novoa R, Wang E, Chen M. Folliculocentric Mycosis Fungoides Masquerading as Angioedema and Allergic Contact Dermatitis. J Allergy Clin Immunol Pract. 2024;12(7):1905-1906. doi:10.1016/j.jaip.2024.04.017
[109] Schaefer L, Comfere N, Sokumbi O. Development of Cutaneous T-Cell Lymphoma Following Biologic Treatment: A Systematic Review. Am J Clin Dermatol. 2023;24(2):153-164. doi:10.1007/s40257-022-00749-1
[110] Pierog O, Talluru SM, Munjal A, Weiner D, Fazal M, Ly A, Rozati S. 44588: Clinical outcomes and characteristics in CTCL patients with a diagnosis of eczema: retrospective review at a single tertiary referral center. J Am Acad Dermatol. 2023;89(3):AB136.

institutions – who had developed mycosis fungoides after starting Dupixent treatment for atopic dermatitis.[111] The 5 institutional patients were treated with Dupixent for an average of 8.4 months prior to developing mycosis fungoides. Mycosis fungoides was diagnosed at stage I in 2 patients and stage II in 1 patient, while 2 patients progressed to Sézary syndrome. The average length of Dupixent treatment prior to mycosis fungoides diagnosis among the 20 literature cases was 11.2 months. The authors advocated for "[c]lose monitoring of these patients and further investigation of the relationship between dupilumab and [mycosis fungoides]".

140. In August 2023, clinicians from Italy published a retrospective analysis of atopic dermatitis patients treated at two Italian tertiary care centers.[112] Between June 2018 and June 2023, 995 patients with atopic dermatitis had been administered Dupixent, 91.8% with a classic atopic dermatitis phenotype and 8.1% with a prurigo nodularis-like phenotype. Seven patients who were unresponsive to Dupixent or exhibited atypical clinical features discontinued treatment and were further studied through skin biopsy and T-cell receptor gamma gene rearrangement analysis. Two of these patients, males aged 55 and 85 years, developed histologically confirmed CTCL after 11 and 19 months of Dupixent treatment. One was diagnosed with mycosis fungoides stage I and treated with ultraviolet therapy with partial response, while the other was diagnosed with progressive Sézary syndrome stage IV and ultimately died before initiating treatment.

141. Researchers from Memorial Sloan Kettering Cancer Center published a descriptive cohort study of CTCL in Dupixent-treated patients as an abstract in November 2023 and in

[111] Hamp A, Hanson J, Schwartz RA, Lambert WC, Alhatem A. Dupilumab-associated mycosis fungoides: a cross-sectional study. Arch Dermatol Res. 2023;315(9):2561-2569. doi:10.1007/s00403-023-02652-z

[112] Buffon S, Alberti Violetti S, Avallone G, et al. Mycosis fungoides and Sézary syndrome following dupilumab treatment: experience of two Italian tertiary care centres. Clin Exp Dermatol. 2023;48(12):1376-1378. doi:10.1093/ced/llad277

updated, final form in May 2024.[113] In this study, researchers identified 27 patients presenting to their center with new mycosis fungoides after being treated with Dupixent for atopic dermatitis. In 16 patients, atopic dermatitis was confirmed through skin biopsy, while the remaining subjects were diagnosed based on clinical features. All patients had worsening symptoms following Dupixent use, and the median duration of Dupixent use prior to CTCL diagnosis was 10.2 months. Mycosis fungoides was diagnosed as stage I (n=16), stage II (n=4), stage III (n=2) or stage IV (n=5) after Dupixent treatment. Authors remarked that the relationship between Dupixent and CTCL deserves a dedicated biological study.

142. In November 2023, researchers from The Netherlands published a case series describing lymphoid reactions mimicking CTCL in 14 patients treated with Dupixent.[114] Three of these patients were retrospectively diagnosed as having preexisting CTCL, each of which experienced clinical worsening of CTCL in response to Dupixent treatment. Despite serving as KOLs for Defendants, these authors found their study highlighted a "need for caution in continuing dupilumab treatment in patients with AD with clinical worsening and newly reported symptoms (eg, burning sensation) after initial adequate response because these patients might develop an LR", while further warning that "these benign LRs may evolve into CTCL if dupilumab treatment is not permanently stopped". Finally, these authors recommended histopathologic evaluation including immunohistochemical staining in specific patients prior to prescribing Dupixent.

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[113] Stuver R, Dusza S, Epstein-Peterson ZD, et al. Cutaneous T-cell lymphoma and dupilumab use: A retrospective matched cohort study of clinical characteristics and treatment outcomes. J Eur Acad Dermatol Venereol. 2025;39(2):e114-e117. doi:10.1111/jdv.20141; Stuver R, Dusza S, Epstein-Peterson ZD, Ghione P, Johnson W, Moskowitz A, Myskowski P, Pulitzer M, Horwitz SM, Geller S. Cutaneous T-Cell Lymphoma and Dupilumab Use: A Retrospective Matched Cohort Study of Clinical Characteristics and Treatment Outcomes. Blood. 2023;142:6184 (abstract).

[114] Boesjes CM, van der Gang LF, Bakker DS, et al. Dupilumab-Associated Lymphoid Reactions in Patients With Atopic Dermatitis. JAMA Dermatol. 2023;159(11):1240-1247. doi:10.1001/jamadermatol.2023.3849

143. In an editorial commenting on the study by Boesjes and colleagues, a dermatologist from Northwestern University Feinberg Medical School noted that the observation of a patient with both CTCL and lymphoid reaction "rais[ed] concerns that [lymphoid reaction] may not be reversible in all cases, but rather an initial step toward lymphoma".[115] The author further advised "dermatologists should remain vigilant in ruling out [mycosis fungoides], particularly in atypical presentations", and that "[i]n such cases, skin biopsy should be the first step prior to dupilumab prescription".

144. At the March 2024 Annual Meeting of the American Academy of Dermatology, researchers from Johns Hopkins University School of Medicine presented the results of a single center retrospective study investigating clinical presentation and outcomes of patients with CTCL following the use of biologics.[116] These clinicians reviewed 148 patients with mycosis fungoides or Sézary syndrome and a documented history of atopic dermatitis at least 2 years prior to CTCL diagnosis, identifying 19 who had undergone treatment with biologics, including adalimumab, apremilast, dupilumab (Dupixent), risankizumab, upadacitinib or ustekinumab, for an average of 2.03 years prior to their CTCL diagnosis. CTCL patients treated with biologics including Dupixent demonstrated more frequent advanced-stage CTCL (III to IV) at diagnosis (52.9% vs 15.1%; p=0.001) and large cell transformation (26.3% vs. 9.3%; p=0.033) compared to CTCL patients who had not been treated with biologics. These researchers concluded their results suggested atopic dermatitis patients treated with biologics like Dupixent could increase the risk of advanced-stage and aggressive CTCL, and that "[t]here may be patients on biologics at risk for developing

[115] Guitart J. Dupilumab, Atopic Dermatitis, and Mycosis Fungoides-New Insights on an Evolving Story. JAMA Dermatol. 2023;159(11):1177-1178. doi:10.1001/jamadermatol.2023.3846

[116] Fleischli A, Pierog O, Rozati S. 54697: Clinical presentation and outcomes of Cutaneous T-cell Lymphoma patients following the use of biologic therapies: retrospective review at a single tertiary referral center. J Am Acad Dermatol. 2024;91(3):AB26.

or unmasking CTCL".

145. Johns Hopkins University School of Medicine researchers presented a similar study at the 5th World Congress of Cutaneous Lymphomas in April 2024, this time comparing the presentation and outcomes of CTCL between patients treated with Dupixent and other biologic therapies.[117] Of 148 patients diagnosed with mycosis fungoides or Sézary syndrome between January 2011 and July 2023 and having a documented history of atopic dermatitis at least 2 years prior to CTCL diagnosis, 19 patients were identified as having been previously treated with biologics, including 9 with Dupixent only, 4 with a combination of Dupixent and other biologics and 6 with biologics other than Dupixent. These researchers found that patients treated with Dupixent were at a significantly higher risk of advanced-stage CTCL at the time of diagnosis ($p<0.001$) and patients treated with a combination of Dupixent and other biologics were at a significantly higher risk of CTCL progression following initial diagnosis ($p=0.04$). The authors advised "[a] thorough clinical work up should be considered prior to initiating treatment with biologic agents for chronic benign inflammatory disease to establish a clear diagnosis and patients should be monitored throughout their treatment course for signs of disease transformation".

146. Researchers from Korea and Germany investigated clinical and pathological features in atopic dermatitis patients who exhibited an inadequate response to Dupixent treatment and published their findings in April 2024.[118] Of 371 patients treated with Dupixent for severe atopic dermatitis, 46 (12.3%) were classified as inadequate responders. Thirty-five of these patients underwent additional evaluation, and of those, 19 (54.2%) were found to have developed

[117] Fleischli A, Pierog O, Yenokyan G, Bao A, Rozati S. Abstract #183: Presentation and outcomes of cutaneous T-cell lymphoma following the use of dupilumab compared to other biologic therapies. 5th World Congress of Cutaneous Lymphomas, April 11 to 13, 2024. Pasadena, California.
[118] Kook H, Gwag HE, Park SY, et al. Detecting T-cell receptor clonality in patients with severe atopic dermatitis refractory to dupilumab. J Eur Acad Dermatol Venereol. 2024;38(10):1939-1946. doi:10.1111/jdv.20053

mycosis fungoides following treatment with Dupixent. These authors concluded that an inadequate response to Dupixent treatment may be an indicator of early mycosis fungoides development in patients with atopic dermatitis.

147. Another case report involving mycosis fungoides developing in a 76-year-old male patient following initiation of Dupixent was published in September 2024.[119] This patient had a 7-year history of atopic dermatitis confirmed through biopsy and characterized by pruritus, chronic and relapsing course of the disease, family history of atopy, xerosis, nonspecific hand eczema and pruritus after sweating. During the 10th week of Dupixent treatment the patient developed erythroderma and significant facial and lower limb edema, and was admitted for management of exacerbated skin symptoms "likely attributed to an outbreak during dupilumab treatment". Based on the results of several tests, the patient was ultimately diagnosed with mycosis fungoides.

148. In December 2024, researchers from Tulane University School of Medicine published a descriptive analysis of patients diagnosed with CTCL at their facility between 2021 and 2023.[120] Of 136 new CTCL cases during the study period, 18 had been treated with Dupixent prior to their CTCL diagnosis. Most patients had adult-onset atopic dermatitis (89%) for a mean duration of 7.17 years and no prior history of treatment with immunosuppressive therapies (72%). Pre-treatment atopic dermatitis diagnoses were confirmed through biopsy in half of the patients, and the mean length of Dupixent treatment before diagnosis of CTCL was 8.1 months. Following treatment with Dupixent, 33% of patients developed erythroderma and 22% developed tumors,

[119] Cisoń H, Cisoń W, Białynicka-Birula B, Suseł M, Białynicki-Birula R, Szepietowski JC. Mycosis fungoides unveiled following dupilumab treatment in a patient with a history of atopic dermatitis. Usefulness of HFUS in monitoring skin features. A review with a case report. Postepy Dermatol Alergol. 2025;42(1):5-12. doi:10.5114/ada.2024.143463

[120] Accetta J, Gioe R, Falgout L, Chastain W, Bitar C, Boh E. Cutaneous T cell lymphoma arising in patients treated with dupilumab: A case series of 18 patients. J Am Acad Dermatol. 2025;92(4):924-926. doi:10.1016/j.jaad.2024.10.119

and CTCL was classified as stage II or higher in 61%. Researchers concluded by commenting that their "study adds 18 patients to the body of evidence linking dupilumab with CTCL".

149. Researchers from Memorial Sloan Kettering Cancer Center published a descriptive cohort study investigating associations between biologic therapies, atopic dermatitis and CTCL in February 2025.[121] Researchers identified all cases presenting to their cutaneous lymphoma clinical with new confirmed diagnosis of CTCL following use of Dupixent, a Janus Kinase inhibitor (JAKi) or the IL-13 inhibitor tralokinumab since 2011. Among 32 total CTCL cases, all 32 (100%) had been treated with Dupixent before being diagnosed with CTCL, 2 (6.25%) of whom had been first treated with the JAKi upadacitinib and then Dupixent before being diagnosed with CTCL. All cases had been diagnosed with atopic dermatitis (n=30) or eczematous rash (n=2), with 22 of the atopic dermatitis/eczema diagnoses being confirmed by an outside dermatologist via skin biopsy. Researchers reevaluated 5 of the 22 skin biopsies and re-confirmed 4 (80%) as pathologic atopic dermatitis, while only in 1 case they changed the pre-treatment diagnosis to mycosis fungoides. The authors concluded that the lack of any cases of CTCL following JAKi alone or tralokinumab in their institution "challenge[s] the hypothesis that severe chronic AD is the cause of CTCL in patients exposed to dupilumab".

150. Owing to accumulating reports describing the development and progression of CTCL in patients treated with Dupixent, independent researchers began conducting systematic reviews of published case reports and case series and publishing their findings as early as 2021. These included a systematic review of 19 cases from 10 studies published in March 2021,[122] a

[121] Liao V, Lavin L, Pulitzer MP, Stuver R, Geller S. Diagnosis of cutaneous T-cell lymphoma following exposure to biologic agents for atopic dermatitis: A retrospective cohort study from a single tertiary cancer center. J Am Acad Dermatol. 2025;92(6):1394-1395. doi:10.1016/j.jaad.2025.01.088
[122] Sugaya M. Is blocking IL-4 receptor alpha beneficial for patients with mycosis fungoides or Sézary syndrome?. J Dermatol. 2021;48(5):e225-e226. doi:10.1111/1346-8138.15834

systematic review of 23 cases from 13 studies published in December 2021,[123] a systematic review of 27 cases from 12 studies published in September 2022,[124] a systematic review of 23 cases from 11 studies published in December 2022[125] and a systematic review of 30 cases from 18 studies published in December 2024.[126] In one of these systematic reviews of Dupixent CTCL case reports the authors remarked, "Interestingly, progression of [Sézary syndrome] has been frequent, considering the rarity of the disease".[127]

151. Researchers from China presented a case series of 3 patients who developed CTCL after starting Dupixent in April 2025.[128] These patients were between 39 and 60 years of age, and each was prescribed Dupixent to treat adult-onset atopic dermatitis. All 3 patients experienced new and worsening symptoms after receiving 2 to 12 Dupixent doses and were eventually diagnosed with mycosis fungoides (2 patients) or Sézary syndrome (1 patient). In reviewing the available scientific literature, these authors found 19 published reports involving 31 patients with atopic dermatitis who had been treated with biologics and subsequently developed CTCL, including 27 (87.10%) that were treated with Dupixent. Ultimately, these researchers concluded that their "observations suggest that dupilumab may play a role in the onset and progression of CTCL".

152. In a May 2025 systematic review of CTCL cases reported in Dupixent users,

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[123] Kołkowski K, Trzeciak M, Sokołowska-Wojdyło M. Safety and Danger Considerations of Novel Treatments for Atopic Dermatitis in Context of Primary Cutaneous Lymphomas. Int J Mol Sci. 2021;22(24):13388. Published 2021 Dec 13. doi:10.3390/ijms222413388

[124] Park A, Wong L, Lang A, Kraus C, Anderson N, Elsensohn A. Cutaneous T-cell lymphoma following dupilumab use: a systematic review. Int J Dermatol. 2023;62(7):862-876. doi:10.1111/ijd.16388

[125] Jfri A, Smith JS, Larocca C. Diagnosis of mycosis fungoides or Sézary syndrome after dupilumab use: A systematic review. J Am Acad Dermatol. 2023;88(5):1164-1166. doi:10.1016/j.jaad.2022.12.001

[126] Guo S, Wang L, Bu D, Liu F. Tumors in the setting of dupilumab use: A review of the literature. World Allergy Organ J. 2024;18(1):101006. Published 2024 Dec 11. doi:10.1016/j.waojou.2024.101006

[127] Sugaya M. Is blocking IL-4 receptor alpha beneficial for patients with mycosis fungoides or Sézary syndrome?. J Dermatol. 2021;48(5):e225-e226. doi:10.1111/1346-8138.15834

[128] Li T, Wang G, Zhang C, Wang W, Li C, Wang Y. Case Report: Cutaneous T-cell lymphoma associated with biologic therapy: three cases and a literature review. Front Med (Lausanne). 2025;12:1544912. Published 2025 Apr 28. doi:10.3389/fmed.2025.1544912

researchers aggregated and described the characteristics of 124 subjects profiled across 29 different case reports, case series and cross-sectional studies.[129] Subjects had a median age of 57.3 years (SD ± 15.7) at the time of lymphoproliferative disorder diagnosis. Most subjects were diagnosed with early-stage mycosis fungoides (n=57; 45.97%), while a considerable proportion were diagnosed with advanced-stage mycosis fungoides or Sézary syndrome (n=41; 33.06%). Median time from Dupixent initiation to biopsy-confirmed lymphoproliferative disorder was 5 months. Of 121 patients initially diagnosed with atopic dermatitis, only 6 were retrospectively diagnosed as having CTCL instead of atopic dermatitis. Three additional patients were initially diagnosed with mycosis fungoides and treated with Dupixent off-label. All 9 patients initially or retrospectively diagnosed with CTCL demonstrated clinical or histopathological progression, with 6 in the advanced stage.

153. As postmarketing case reports, case series and descriptive observational studies evidencing a strong risk of CTCL with Dupixent use amassed, researchers expressed concern, advised caution and strongly recommended that atopic dermatitis patients undergo multiple skin biopsies to rule out underlying cutaneous malignancy prior to prescribing Dupixent. Furthermore, these clinicians recommended ongoing monitoring and repeat screening through serial biopsies and other means to detect changes in pathology during the course of Dupixent treatment that may be indicative of disease transformation. Additionally, researchers advised healthcare providers to maintain a high degree of clinical suspicion for CTCL when a patient shows signs of non-responsiveness or brief, initial responsiveness to Dupixent treatment followed by exacerbation of symptoms. Despite these calls from researchers year after year, Defendants provided no such

[129] Li M, Zhao W, Lai P, Xiao Y, Wang Y. Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. Curr Opin Immunol. 2025;94:102563. doi:10.1016/j.coi.2025.102563

recommendations to aid in the appropriate screening and monitoring of patients to reduce or eliminate the risk of Dupixent-induced or Dupixent-exacerbated CTCL.

154. On the contrary, Defendants, via their retained KOLs, actually advocated for *increased* usage of Dupixent when the FDA-approved dosing regimen proved inadequate to relieve symptoms of atopic dermatitis. Peter A. Lio, MD, an investigator, speaker, advisory board member and consultant for Defendants, and Vivian Y. Shi, MD, an investigator and advisor for Defendants, along with their colleague Aleski Hendricks, published an article in 2019 recommending more aggressive prescribing of Dupixent, including increased dosages, increased dosing frequency and the addition of immunosuppressive agents to existing Dupixent regimens, in circumstances when patients exhibit an inadequate or incomplete response to Dupixent treatment.[130] Notably, despite claiming "[t]here were no incentives or transactions financial or otherwise relevant to this manuscript", in just 2018 and 2019, Defendants paid Peter A. Lio, MD $306,404 in general payments and paid Vivian Y. Shi, MD $69,300 in general payments. The above recommendations for more aggressive prescribing of Dupixent in patients exhibiting an inadequate or incomplete response to treatment were echoed in another "expert panel" report funded by Defendants and authored by KOLs retained by Defendants which was published in 2021.[131]

155. Furthermore, all times relevant hereto, Defendants' branded marketing materials and branded websites for Dupixent have expressly advertised "NO INITIAL LAB TESTING OR ONGOING LAB MONITORING" is required for prescription and treatment with

[130] Hendricks AJ, Lio PA, Shi VY. Management Recommendations for Dupilumab Partial and Non-durable Responders in Atopic Dermatitis. Am J Clin Dermatol. 2019;20(4):565-569. doi:10.1007/s40257-019-00436-8

[131] Papp KA, Hong CH, Lansang MP, et al. Practical Management of Patients with Atopic Dermatitis on Dupilumab. Dermatol Ther (Heidelb). 2021;11(5):1805-1828. doi:10.1007/s13555-021-00586-w

Dupixent.[132,133,134,135] Atopic dermatitis clinical treatment guidelines funded by Defendants have similarly touted "[n]o laboratory monitoring is required before initiation or during treatment" with Dupixent.[136,137]

c. Analytic Cohort Studies

156. In addition to the extensive body of published case reports, case series and descriptive observational studies, a strong causal relationship between Dupixent and CTCL is supported by several large, high-quality analytical cohort studies of patients with atopic dermatitis and asthma.

157. On April 6, 2024, researchers from the West Virginia University School of Medicine published an analytical cohort study (the "Hasan 2024 study") in which they leveraged data from TriNetX, a large deidentified electronic health record (EHR) database containing clinical observations and other information on over 275 million patients, to compare the risk of CTCL and

[132] DUPIXENT Specialist Referral, *Dupixent Partnering With a Specialist Brochure* (PDF), https://www.dupixentspecialistreferral.com/assets/pdfs/US.DUP.24.09.0134_DUPIXENT_AD-PCP-PED_FAQ_Brochure.pdf (last visited Dec. 10, 2025).
[133] DUPIXENT, *DUP AD Patient Profile* (Aug. 2022), https://www.dupixent.com/dam/jcr:777e1c3f-5c75-4ec4-a2d4-d6eb546f7a52/DUP.22.08.0105%20DUP%20AD%20Patient%20Profile_Ore_Aug%202022%20Update.pdf (last visited Dec. 10, 2025).
[134] DUPIXENT, *Atopic Dermatitis*, https://www.dupixenthcp.com/atopicdermatitis/ (last visited Dec. 10, 2025).
[135] DUPIXENT, Safety/Clinical Trial, Demonstrated Long-Term Safety Profile https://www.dupixenthcp.com/atopicdermatitis/efficacy-safety/safety-clinical-trial (last visited Dec. 10, 2025).
[136] Simpson EL, Bruin-Weller M, Flohr C, et al. When does atopic dermatitis warrant systemic therapy? Recommendations from an expert panel of the International Eczema Council. J Am Acad Dermatol. 2017;77(4):623-633. doi:10.1016/j.jaad.2017.06.042
[137] Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102

other malignancies among atopic dermatitis patients treated or not treated with Dupixent.[138] Two separate models were developed using propensity score matching to control for potential confounders. In the first model adjusting for age only, Dupixent-treated subjects exhibited over a 300% increased risk of developing CTCL (OR 4.10; 95% CI 2.06-8.19) compared to untreated subjects. The observed statistically significant association persisted after excluding subjects with prior disease-modifying antirheumatic drug use and controlling for age, sex, ethnicity and race, with Dupixent use increasing the risk of CTCL among atopic dermatitis patients by 220% (OR 3.20; 95% CI 1.57-6.51).

158. Also utilizing data from TriNetX, another analytical cohort study investigating CTCL risk with use of Dupixent was published on August 14, 2024 by researchers from Thomas Jefferson University.[139] In this study (the "Mandel 2024 study"), authors first excluded all subjects with a history of inflammatory conditions and use of biologics with evidence of a possible association with lymphoma. After controlling for age at the time of atopic dermatitis diagnosis, race and sex through propensity score matching, Dupixent-treated atopic dermatitis patients were found to be at a 359% increased risk of CTCL (RR 4.59; 95% CI 2.46-8.57) compared to atopic dermatitis patients not treated with Dupixent.

159. Another analytical cohort study (the "Sheng-Kai Ma 2025 study") was published in June 2025 by researchers from Harvard Medical School, Massachusetts General Hospital, Boston Children's Hospital and Harvard T.H. Chan School of Public Health.[140] These researchers used

[138] Hasan I, Parsons L, Duran S, Zinn Z. Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T cell lymphoma: A retrospective cohort study. J Am Acad Dermatol. 2024;91(2):255-258. doi:10.1016/j.jaad.2024.03.039

[139] Mandel J, Mehta J, Hafer R, et al. Increased Risk of Cutaneous T-Cell Lymphoma Development after Dupilumab Use for Atopic Dermatitis. Dermatol Ther. 2024;2024:9924306. doi:10.1155/2024/9924306

[140] Sheng-Kai Ma K, Brumbaugh B, Saff RR, et al. Dupilumab and lymphoma risk among patients with asthma: a population-based cohort study. Eur Respir J. 2025 (Ahead-of-Print). doi:10.1183/13993003.00139-2025

data from TriNetX to compare hematological malignancy risk among asthma patients initiating treatment with Dupixent with those treated with combination inhaled corticosteroids and long-acting beta agonists (ICS/LABA) while excluding patients with a history of atopic dermatitis. Before adjustment, Dupixent-treated asthma patients had a significantly increased risk of CTCL (HR 5.97; 95% CI 2.75-12.97), mycosis fungoides and Sézary syndrome (HR 5.62; 95% CI 2.72-11.59) and peripheral T-cell lymphoma (HR 5.61; 95% CI 2.71-11.59) compared to ICS/LABA asthma patients. A greedy nearest-neighbor propensity score matching algorithm was used to control for age, sex, socioeconomic status, comorbidities, concomitant medications, substance use and healthcare utilization prior to treatment initiation. Results were nearly identical after propensity score matching, with a significant increased risk of CTCL (HR 5.63; 95% CI 1.16-27.37), mycosis fungoides and Sézary syndrome (HR 5.79; 95% CI 1.22-27.42) and peripheral T-cell lymphoma (HR 6.14; 95% CI 1.29-29.17) among Dupixent patients. Dupixent was also associated with a higher risk of any lymphoma (HR 1.79; 95% CI 1.19-2.71) and combined mature T and NK cell lymphomas (HR 4.58; 95% CI 1.82-11.53).

160. Researchers from Columbia University, the University of Illinois, Drexel University and the University of Louisville published the results of another analytical cohort study investigating CTCL risk with Dupixent use as a research letter (the "Ahmed 2026 research letter") on January 3, 2026.[141] Using data from TriNetX, these authors created separate cohorts of patients initiating Dupixent or upadacitinib or ruxolitinib following a diagnosis of atopic dermatitis, after excluding patients with prior diagnoses of CTCL and other malignancies. Each of the study groups were independently propensity score matched to atopic dermatitis patients not treated with a

[141] Ahmed A, Wambold D, Burshtein J. et al. Risk of cutaneous T-cell lymphoma in atopic dermatitis patients treated with dupilumab and JAK inhibitors: a TriNetX cohort study. Arch Dermatol Res. 2026;318(37). doi:10.1007/s00403-025-04501-7

biologic medication based on age, sex, race and ethnicity, to compare CTCL risk. Significantly greater odds of incident CTCL were observed among patients treated with Dupixent compared to patients not treated with a biologic (OR 2.86; 95% CI 1.93-4.22), with 1 estimated CTCL case for every 424 Dupixent-treated patients. In contrast, neither upadacitinib nor ruxolitinib – medications which both carry boxed warnings regarding lymphomas and other malignancies – were significantly associated with CTCL relative to non-use of biologics. Over half of the CTCL cases in Dupixent-treated patients developed >1 year after initiating treatment, suggesting unmasking of preexisting disease was unlikely to explain the association observed among this cohort. The authors concluded their findings "reinforce previous reports linking dupilumab to increased CTCL risk in AD patients", and that "the observed association between dupilumab and CTCL, with a relatively low NNH, underscores the importance of ongoing clinical vigilance".

161. Clinicians from Orange Park Hospital in Florida, Texas A&M College of Medicine and various private dermatology clinics and medical centers in Dallas, Texas published another analytical cohort study using TriNetX data as a research letter (the "Talasila 2026 research letter") on January 23, 2026.[142] These authors excluded patients with a history of immunodeficiency disorders, systemic malignancy, organ transplantation or off-study biologic exposure and used propensity scoring to match Dupixent users to non-Dupixent users based on demographic factors, immunosuppressant use and relevant comorbidities. Study cohorts were further stratified by age (18-59 years and ≥60 years) before comparing risk of subsequent mycosis fungoides diagnosis by Dupixent exposure status. Among atopic dermatitis patients aged 18-59 years, Dupixent use was associated with a significant increased risk of mycosis fungoides at 1 year (RR 2.18; 95% CI 1.08-

[142] Talasila S, Nadir U, Jeha GM, Tolkachjov SN. Diagnostic Implications of Dupilumab-Refractory Atopic Dermatitis: Risk of Underlying Cutaneous T-Cell Lymphoma and the Role of Skin Biopsy. Int J Dermatol. Published online January 23, 2026. doi:10.1111/ijd.70307

4.40), 5 years (RR 2.38; 95% CI 1.34-4.25) and 10 years (RR 2.35; 95% CI 1.34-4.14) relative to Dupixent non-use. Dupixent users aged ≥60 years similarly experienced a significant increased risk of mycosis fungoides relative to non-users at 1 year (RR 2.06; 95% CI 1.13-3.75), 5 years (RR 2.17; 95% CI 1.38-3.42) and 10 years (RR 1.97; 95% CI 1.30-2.87).

162. On February 23, 2026, researchers from the University of California San Diego published the results of a retrospective single-center cohort study examining CTCL risk in relation to Dupixent use (the "Baghdasarian 2026 brief report").[143] Electronic health records maintained in the University of California San Diego Health system were used to identify patients with (n=1,374) or without (n=1,249,409) a history of Dupixent treatment and to ascertain incident cases of CTCL among groups, defined by diagnosis codes for mycosis fungoides or Sézary syndrome. Patients with preexisting CTCL were excluded from the cohort and cases in the Dupixent group were not considered unless they were diagnosed at least three months after Dupixent initiation. During the study period, the absolute risk of CTCL among Dupixent and non-Dupixent patients was 0.22% and 0.042%, respectively. Using multivariable logistic regression models to adjust for age, sex, race, baseline atopic dermatitis, pain, rash, history of cutaneous squamous cell carcinoma and protocolized follow-up, these researchers found that Dupixent use was associated with 87% increased odds of CTCL (OR 1.87; 95% CI 1.08-3.23;[144] p=0.025) compared to non-use. History of atopic dermatitis was not significantly associated with CTCL. The authors recommended vigilant baseline assessment and ongoing monitoring when initiating Dupixent, advising that physicians should exercise a low threshold for biopsy in atypical or refractory cases of atopic

[143] Baghdasarian S, Al-Saedi O, Cuomo RE. Dupilumab and Cutaneous T-Cell Lymphoma: A Retrospective Cohort Study. JAAD Int. 2026. (Ahead-of-Press). doi:10.1016/j.jdin.2026.02.004

[144] An odds ratio and p value were presented in the publication while a confidence interval around the odds ratio was not reported. This 95% confidence interval was constructed using data provided in Table 2 in the manuscript, operating under the presumption that "Error" reflects the standard error of the beta parameter from the logistic model.

dermatitis and perform interval reassessments during Dupixent therapy.

d. Disproportionality Analyses

163. The FDA and all major foreign health authorities collect spontaneous reports involving adverse drug events, medication errors and product quality issues submitted by patients, healthcare providers and sponsors of pharmaceutical products. In the United States, the FDA collects and stores these reports in the FDA Adverse Event Reporting System (FAERS). It is mandatory for pharmaceutical sponsors to timely submit any adverse events it receives to the FDA. Patients and healthcare providers submit reports on a voluntary basis, either directly to the FDA or to pharmaceutical companies who are then required to forward them to the FDA. These reports are coded using the Medical Dictionary for Regulatory Activities (MedDRA), a formal, hierarchical language which assigns specific reaction preferred terms to reported adverse events.

164. Spontaneous adverse events serve as a foundation for the detection of emerging safety signals for pharmaceutical products. Pharmaceutical sponsors and independent researchers commonly analyze adverse events using statistical measures that quantify the degree of disproportionality between observed and expected reporting frequencies of drug-event combinations. Two common disproportionality statistics include the reporting odds ratio (ROR) and proportional reporting ratio (PRR), which are interpreted in a similar manner to that of the odds ratio and risk ratio, respectively. The higher the ROR or PRR, the greater the extent to which the reporting of a given adverse event is observed to be disproportionately reported with a given drug. Like odds ratios and risk ratios, RORs and PRRs are typically accompanied by 95% confidence intervals to indicate precision and statistical significance of the disproportionality estimate. A report of an adverse event necessarily comes with it suspicion that there is an association between the drug used and event experienced. Reporters indicate the suspected role of

a drug in an observed adverse event using one of the following designations: primary suspect, secondary suspect, concomitant or interacting product. A primary suspect product is one which the reporter believes is most likely responsible for the observed adverse event. A secondary suspect product is one which the reporter believes may have contributed to the observed adverse event, but which is less likely to be responsible than the drug designated the primary suspect.

165. To date, six published disproportionality analyses have reported a positive safety signal for CTCL in association with Dupixent based on postmarketing adverse event reports.

166. The first disproportionality analysis (the "Mota 2023 study") was initially published in an online preprint on August 1, 2022 and subsequently on December 26, 2022 after undergoing peer review.[145] In this study, researchers from Portugal analyzed data from VigiBase, the pharmacovigilance database maintained by the World Health Organization, to investigate potential safety signals for various cancers with therapeutic biologics targeting IL-5 and IL-4 receptor alpha based on postmarketing adverse event reporting. Based on reports submitted to VigiBase between 2008 and 2020, this study identified a positive disproportionality signal for CTCL with Dupixent as reflected by a statistically significant ROR of 11.11 (95% CI 6.77-18.23). This finding indicates patients were over 10 times more likely to report CTCL as an adverse event with Dupixent than other medications between 2008 and 2020.

167. The second disproportionality analysis (the "Lavin 2025 study") was published by researchers from Memorial Sloan Kettering Cancer Center on June 28, 2024.[146] This study utilized data from FAERS to evaluate CTCL reporting with Dupixent and other biologics used in the

[145] Mota D, Rama TA, Moreira A. Real-world evidence on the risk of cancer with anti-IL-5 and anti-IL-4Ra biologicals. Allergy. 2023;78(5):1375-1377. doi:10.1111/all.15628

[146] Lavin L, Dusza S, Geller S. Cutaneous T-Cell Lymphoma after Dupilumab Use: A Real-World Pharmacovigilance Study of the FDA Adverse Event Reporting System. J Invest Dermatol. 2025;145(1):211-214.e1. doi:10.1016/j.jid.2024.06.1272

treatment of dermatological conditions, and performed separate analyses of reports submitted involving a single medication (monotherapy analysis) and reports involving multiple suspect medications (polytherapy analysis). Ultimately, in analyzing adverse event reports submitted to the FDA between the first quarter of 2017 and fourth quarter of 2024, these researchers observed significant signals of disproportionate CTCL reporting with Dupixent in both monotherapy (ROR 8.81; 95% CI 7.10-10.90) and polytherapy (ROR 10.35; 95% CI 8.50-12.60) analyses. These results demonstrate Dupixent was approximately 8 to 10 times as likely to be identified as a primary suspect product in CTCL adverse event reports submitted between 2017 and 2024 as compared to other medications.

168. The third disproportionality analysis (the "Cabrera-Perez 2025 study") also used data from FAERS and was published by researchers from Brigham & Women's Hospital, Harvard Medical School, Dana-Farber Cancer Institute, UMass Chan Medical School, Massachusetts General Hospital and Massachusetts Institute of Technology on November 7, 2024.[147] These researchers observed extremely strong disproportionality signals with Dupixent for CTCL (PRR 29.96; 95% CI 25.02-35.87), CTCL stage I (PRR 277.00; 95% CI 118.41-648.03), CTCL stage II (PRR 103.26; 95% CI 41.20-258.82), CTCL stage III (PRR 383.54; 95% CI 115.49-1,273.73) and CTCL stage IV (PRR 1,246.52; 95% CI 281.29-5,523.87) based on reporting to FAERS between the first quarter of 2017 and fourth quarter of 2024. The findings of this disproportionality analysis indicate that various stages of CTCL were anywhere from 29 to over 1,200 times more likely to be reported to FAERS in association with Dupixent than other medications between 2017 and 2024.

[147] Cabrera-Perez JS, Carey VJ, Odejide OO, et al. Integrative epidemiology and immunotranscriptomics uncover a risk and potential mechanism for cutaneous lymphoma unmasking or progression with dupilumab therapy. J Allergy Clin Immunol. 2025;155(5):1584-1594. doi:10.1016/j.jaci.2024.10.028

169. The fourth disproportionality analysis (the "Gao 2025 study") was published in March 2025 by researchers from Jiangyin People's Hospital in China.[148] Utilizing FAERS data covering the second quarter of 2017 through the fourth quarter of 2023, this study identified significant safety signals for CTCL stage III (ROR 35.83; 95% CI 13.89-92.43) and CTCL stage IV (ROR 33.78; 95% CI 16.52-69.11) among reports in which Dupixent was identified as a primary suspect product. These results indicate Dupixent was over 30 times more likely than other medications to be identified as a primary suspect product in cases of CTCL stage III and IV reported to FAERS between 2017 and 2023.

170. In August 2025, the fifth analysis highlighting a disproportionality signal for CTCL with Dupixent (the "Zhou 2025 study") was published.[149] Researchers analyzed adverse event reporting to FAERS between the second quarter of 2017 and fourth quarter of 2024, and stratified reporting by age group (children < 18 years old and adults ≥ 18 years old). Among adults, a strong signal for CTCL stage III and CTCL stage IV reporting was observed with Dupixent, as indicated by RORs of 28.10 (95% CI 13.38-59.02) and 31.11 (95% CI 14.68-65.93), respectively. Consistent with prior disproportionality analyses, the findings of this study show CTCL stage III and IV were approximately 30 times more likely to be reported to FAERS with Dupixent among adults between 2017 and 2024.

171. In May 2026, the sixth analysis highlighting a disproportionality signal for CTCL with Dupixent (the "Lyu 2025 study") was published.[150] These investigators analyzed FAERS

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[148] Gao H, Cao L, Liu C. Analysis and mining of Dupilumab adverse events based on FAERS database. Sci Rep. 2025;15(1):8597. doi:10.1038/s41598-025-92330-z

[149] Zhou J, Xie Y, Du P, Chen M, Liu X. Analysis of differences in dupilumab-associated adverse drug event signals between children and adults based on the FAERS database. Eur J Pharmacol. 2025;1005:178103. doi:10.1016/j.ejphar.2025.178103

[150] Lyu W, Xu R, Chen L, Lie W, Chen C, Liao J, Lin X, Ma R, Wen W, Li H. Neoplasm Adverse Events Associated with Anti-Type 2 Biologics: An FAERS Database Pharmacovigilance Analysis Study. Cancer Medicine. 2026; 15:e71979. Doi.org/10.1002/cam4.71979

database reports for five biologics from their respective market entry dates until the first quarter of 2025 for the asthma indication only. Consistent with the five other disproportionality analyses, Dupixent exhibited a strong and specific signal for CTCL with an ROR of 6.1 (95% CI 1.76-21.06).

e. Spontaneous Postmarketing Adverse Events

172. The foregoing published case reports, case series, cohort studies and disproportionality analyses were not the first sources of notice to Defendants that CTCL was a serious problem with Dupixent following its approval for marketing in the United States by the FDA. Indeed, a review of the FAERS database reveals Defendants received numerous spontaneous postmarketing adverse events of CTCL developing in patients after starting treatment with Dupixent.

173. On March 6, 2018, Defendants received the first postmarketing adverse event involving CTCL associated with Dupixent use. In this case, CTCL developed in a 42-year-old female after starting Dupixent for atopic dermatitis, with CTCL coded under the MedDRA preferred terms Cutaneous T-cell lymphoma and mycosis fungoides (Manufacturer Control # US-SA-2018SA070308; FDA Case ID 14631226). This case was submitted to Defendants by a physician in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the mycosis fungoides reaction and the secondary suspect product in the Cutaneous T-cell lymphoma reaction.

174. On May 31, 2018, Defendants received another postmarketing adverse event involving CTCL in a 49-year-old female after starting Dupixent for atopic dermatitis, coded under the MedDRA preferred terms Cutaneous lymphoma and Anaplastic large cell lymphoma T- and null-cell types (Manufacturer Control # FR-SA-2018SA152895; FDA Case ID 14996226). This

case was submitted to Defendants by a physician in France, and the outcome was coded as involving hospitalization, life-threatening and other serious outcomes. Dupixent was coded the primary suspect product in each of the CTCL reactions. In assessing causality, the reporting physician considered the patient's CTCL to be related to her use of Dupixent.

175. On June 7, 2018, Defendants received another postmarketing adverse event involving T-cell lymphoma in a 58-year-old male after starting Dupixent for atopic eczema, coded under the MedDRA preferred term T-cell lymphoma (Manufacturer Control # DE-SA-2018SA154104; FDA Case ID 15017896). This case was retrieved by Defendants from the EudraVigilance database after being submitted by a physician in Germany, and the outcome was coded as involving life-threatening outcomes. Dupixent was coded the primary suspect product in the reaction.

176. On June 20, 2018, Defendants received another postmarketing adverse event involving T-cell lymphoma in a female patient of unspecified age after starting Dupixent, coded under the MedDRA preferred term T-cell lymphoma (Manufacturer Control # US-SA-2018SA168847; FDA Case ID 15657049). This case was submitted to Defendants by a consumer in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the reaction. Defendants determined that the T-cell lymphoma in this case was related to Dupixent.

177. On June 20, 2018, Defendants received another postmarketing adverse event involving CTCL in a female patient of unspecified age after starting Dupixent, coded under the MedDRA preferred term Cutaneous lymphoma (Manufacturer Control # US-SAKK-2018SA168812AA; FDA Case ID 15662436). This case was submitted to Defendants by a healthcare professional in the United States, and the outcome was coded as involving other serious

outcomes. Dupixent was coded the primary suspect product in the CTCL reaction. Defendants determined that the CTCL in this case was related to Dupixent.

178. On June 28, 2018, Defendants received another postmarketing adverse event involving CTCL in a 49-year-old female after starting Dupixent for atopic dermatitis, coded under the MedDRA preferred term Cutaneous lymphoma (Manufacturer Control # FR-SA-2018SA177287; FDA Case ID 15120678). This case was retrieved by Defendants from the EudraVigilance database after being submitted by a physician in France, and the outcome was coded as involving hospitalization and other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

179. On July 19, 2018, a pharmacist in the United States submitted a postmarketing adverse event directly to the FDA involving CTCL in a 60-year-old male after starting Dupixent, coded under the MedDRA preferred term Cutaneous lymphoma (FDA Case ID 15261101). An outcome code was not provided. Dupixent was coded the primary suspect product in the CTCL reaction.

180. On August 27, 2018, Defendants received another postmarketing adverse event involving CTCL in a 71-year-old male patient after starting Dupixent for atopic dermatitis, coded under the MedDRA preferred term Cutaneous T-cell lymphoma (Manufacturer Control # US-SAKK-2018SA241856AA; FDA Case ID 15361034). This case was submitted to Defendants by a physician in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

181. On September 21, 2018, Defendants received another postmarketing adverse event involving CTCL in a female patient of unspecified age after starting Dupixent for atopic dermatitis, coded under the MedDRA preferred terms Cutaneous T-cell lymphoma, mycosis fungoides and

T-cell lymphoma (Manufacturer Control # US-SA-2018SA266899; FDA Case ID 15453098). This case was submitted to Defendants by a healthcare professional in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in each of the CTCL reactions.

182. On October 23, 2018, Defendants received another postmarketing adverse event involving CTCL in a 69-year-old male patient after starting Dupixent for atopic dermatitis, coded under the MedDRA preferred term Cutaneous T-cell lymphoma (Manufacturer Control # DE-SA-2018SA294020; FDA Case ID 15659024). This case was submitted to Defendants by a physician in Germany, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

183. On November 16, 2018, Defendants received another postmarketing adverse event involving CTCL in a 60-year-old male patient after starting Dupixent, coded under the MedDRA preferred term Cutaneous lymphoma (Manufacturer Control # US-SA-2018SA320596; FDA Case ID 15657860). This case was submitted to Defendants by a consumer in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

184. Ten of the foregoing 11 spontaneous postmarketing adverse event reports of CTCL developing in patients after starting Dupixent were received by Defendants before the publication of the case report by Bozon and colleagues on November 30, 2018, with 1 additional adverse event report being submitted directly to the FDA. Defendants would have expeditiously received a copy of the single report submitted directly to the FDA if they were participants in the FDA's MedWatch-to-Manufacturer program, still in effect at the time this adverse event was reported.

185. Four additional spontaneous postmarketing adverse event reports of CTCL in

patients treated with Dupixent were received by Defendants between the November 30, 2018 publication of Bozon et al. and the publication of the case report by Chiba and colleagues on May 2, 2019.

186. On January 17, 2019, Defendants sent the FDA another postmarketing adverse event it had received involving CTCL in a 62-year-old male after starting Dupixent, coded under the MedDRA preferred term mycosis fungoides (Manufacturer Control # US-SAKK-2019SA011181AA; FDA Case ID 15837889). This case was submitted to Defendants by a physician in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

187. On March 7, 2019, Defendants received another postmarketing adverse event involving CTCL in a 60-year-old male after starting Dupixent for atopic eczema, coded under the MedDRA preferred terms Cutaneous T-cell lymphoma stage IV and mycosis fungoides stage IV (Manufacturer Control # 2019SA065205). According to the narrative, this patient experienced "[r]apid progression of mycosis fungoides to stage 4 disease exacerbation of T-cell lymphoma,rapid progression of ctcl with systemic spread(developed greater than 50 cutaneous tumours)", with "[t]umours popping up daily- very aggressive with rapid progression", and the causal relationship between Dupixent and the reported reaction was considered "probable". The outcome in this case was coded as involving hospitalization, disability, life-threatening and other serious outcomes, and Dupixent was coded the primary suspect product in each of the CTCL reactions.

188. On March 12, 2019, Defendants received another postmarketing adverse event involving CTCL in a male patient of unspecified age after starting Dupixent for atopic dermatitis, coded under the MedDRA preferred terms Cutaneous T-cell lymphoma and mycosis fungoides

(Manufacturer Control # CA-SA-2019SA071375; FDA Case ID 16089199). This case was submitted to Defendants by a physician in Canada, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

189. On April 22, 2019, Defendants received another postmarketing adverse event involving CTCL in a male patient of unspecified age after starting Dupixent for asthma and allergic eczema, coded under the MedDRA preferred term Cutaneous T-cell lymphoma (Manufacturer Control # US-SA-2019SA116239; FDA Case ID 16243025). This case was submitted to Defendants by a consumer in the United States, and the outcome was coded as involving other serious outcomes. Dupixent was coded the primary suspect product in the CTCL reaction.

190. After publication of the Chiba report, spontaneous postmarketing adverse event reports of CTCL developing in patients after starting Dupixent continued to pile up. Ten additional postmarketing adverse event reports of CTCL developing in patients after starting Dupixent were received by Defendants between May 2, 2019 and September 24, 2019, the date Poyner et al. and Yoo et al. presented their respective case reports and Amitay-Laish et al. presented their descriptive study at the 2019 Cutaneous Lymphoma Task Force Meeting of the EORTC.

191. At least 17 further postmarketing adverse event reports of CTCL developing in patients after starting Dupixent were received by Defendants and forwarded to FDA between September 24, 2019 and the publication of the case series by Espinosa and colleagues on March 27, 2020.

192. Through the end of 2020, at least 23 more postmarketing adverse event reports of CTCL developing in patients after starting Dupixent were received by Defendants and forwarded to FDA.

193. In the following years, a steady stream of CTCL adverse events in patients taking

Dupixent continued to flow in. Upon information and belief, over 200 such cases were reported to the Defendants by the end of 2024.

194. Based on well-established principles, these adverse event numbers vastly underestimate the true number of CTCL events occurring with Dupixent use. Additionally, as FDA has made clear in its Guidance to Industry, even a single well-documented post-marketing adverse event report can constitute a safety signal requiring action by the manufacturer, including a potential label change, particularly if the report involves an event that is extremely rare in the absence of drug use.

195. Many of the aforementioned adverse event reports contained causal attributions to Dupixent use by the reporting physicians.

f. Mechanistic Research

196. Defendants did not conduct any experimental carcinogenicity studies of Dupixent in any animal species prior to FDA approval for marketing in the United States.[151] Upon information and belief, Defendants still have not conducted any formal testing to evaluate the carcinogenic properties of Dupixent. Similarly, upon information and belief, Defendants have failed to conduct any formal testing to identify potential mechanisms through which Dupixent exposure might cause severe and rapid progression of subclinical CTCL.

197. Defendants' failure to allocate resources towards studying causal mechanisms of Dupixent-induced CTCL is despite multiple calls to conduct such testing from independent

[151] Center for Drug Evaluation and Research. Pharmacology Reviews: Dupixent (dupilumab). Application Number 761055. U.S. Food and Drug Administration. March 2017

researchers (*e.g.*, "We believe that this relationship deserves a dedicated biological study";[152,153] "current hypotheses still require further validation through in vivo and in vitro experiments, as well as patient sequencing data"[154]) and even Defendants' own paid KOLs ("More studies should be conducted to investigate the association of CTCL with dupilumab therapy, as the currently available data is not sufficient to identify the mechanistic relationship clearly"[155]). Defendants' KOLs even suggested establishing a dedicated database to provide "comprehensive data on clinical features histology, and outcomes of dupilumab-associated CTCL… given the widespread use of dupilumab", yet upon information and belief, Defendants have failed to support any such initiative.[156]

198. As a result of Defendants' failures, the exact mechanism through which Dupixent causes or contributes to the development of CTCL has not yet been discovered. Nonetheless, a causal relationship between use of Dupixent and development or exacerbation of CTCL is biologically plausible and is supported by various lines of clinical and non-clinical research.

199. In the presence of inaction by Defendants to perform necessary testing and research to better understand pathological processes underlying Dupixent-induced CTCL, independent researchers and clinicians have endeavored to investigate plausible mechanisms through which Dupixent can cause CTCL or lead to severe and rapid progression of subclinical CTCL.

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[152] Stuver R, Dusza S, Epstein-Peterson ZD, Ghione P, Johnson W, Moskowitz A, Myskowski P, Pulitzer M, Horwitz SM, Geller S. Cutaneous T-Cell Lymphoma and Dupilumab Use: A Retrospective Matched Cohort Study of Clinical Characteristics and Treatment Outcomes. Blood. 2023;142:6184

[153] Stuver R, Dusza S, Epstein-Peterson ZD, et al. Cutaneous T-cell lymphoma and dupilumab use: A retrospective matched cohort study of clinical characteristics and treatment outcomes. J Eur Acad Dermatol Venereol. 2025;39(2):e114-e117. doi:10.1111/jdv.20141

[154] Li M, Zhao W, Lai P, Xiao Y, Wang Y. Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. Curr Opin Immunol. 2025;94:102563. doi:10.1016/j.coi.2025.102563

[155] Francuzik W, Alexiou A, Worm M. Safety of dupilumab in patients with atopic dermatitis: expert opinion. Expert Opin Drug Saf. 2021;20(9):997-1004. doi:10.1080/14740338.2021.1939673

[156] Beylot-Barry M, Staumont-Salle D. Cutaneous T-Cell Lymphoma and Dupilumab Use: A Multifactorial and Complex Story. J Invest Dermatol. 2025;145(1):9-11. doi:10.1016/j.jid.2024.08.015

200. IL-4 and IL-13, the two primary targets of Dupixent, have been implicated in the pathogenesis of CTCL, with IL-13 and its receptors being highly expressed in the clinically involved skin of CTCL patients.[157,158] Malignant Sézary cells have also been shown to have a T helper 2 cytokine fingerprint with a predominance of IL-13 in addition to IL-4, IL-5 and IL-10.[159] According to one leading theory that has been proposed by researchers, Dupixent's blocking of IL-4 receptor alpha results in increases in the amount of free IL-13, while keratinocytes which would normally act as a sink to absorb excess IL-13 in atopic conditions are also blocked by Dupixent. Consequently, the unbound IL-13 is available to bind at the upregulated IL-13 receptor alpha 2 site on cells and support proliferation of neoplastic T cell clones into full-blown lymphoma.[160,161,162,163] This is important because prior research has identified multiple mechanisms through which free IL-13 can promote growth or survival of certain tumors through direct action on the tumor or suppression of immunosurveillance.[164] Another theory posits that pre-existing chronic skin inflammation, when exposed to a Dupixent-induced immunomodulatory

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[157] Geskin LJ, Viragova S, Stolz DB, Fuschiotti P. Interleukin-13 is overexpressed in cutaneous T-cell lymphoma cells and regulates their proliferation. Blood. 2015;125(18):2798-2805. doi:10.1182/blood-2014-07-590398

[158] Mazzetto R, Miceli P, Tartaglia J, Ciolfi C, Sernicola A, Alaibac M. Role of IL-4 and IL-13 in Cutaneous T Cell Lymphoma. Life (Basel). 2024;14(2):245. Published 2024 Feb 9. doi:10.3390/life14020245

[159] Francuzik W, Alexiou A, Worm M. Safety of dupilumab in patients with atopic dermatitis: expert opinion. Expert Opin Drug Saf. 2021;20(9):997-1004. doi:10.1080/14740338.2021.1939673

[160] Cabrera-Perez JS, Carey VJ, Odejide OO, et al. Integrative epidemiology and immunotranscriptomics uncover a risk and potential mechanism for cutaneous lymphoma unmasking or progression with dupilumab therapy. J Allergy Clin Immunol. 2025;155(5):1584-1594. doi:10.1016/j.jaci.2024.10.028

[161] Guglielmo A, Borghi A, Schettini N, et al. Mycosis fungoides and IL-4/13 inhibitors: what is known and unmet needs. Expert Rev Clin Immunol. 2025;21(6):723-729. doi:10.1080/1744666X.2025.2507332

[162] Li M, Zhao W, Lai P, Xiao Y, Wang Y. Dupilumab-associated lymphoproliferative disorders: a comprehensive review on clinicohistopathologic features and underlying mechanisms. Curr Opin Immunol. 2025;94:102563. doi:10.1016/j.coi.2025.102563

[163] Ong PY. Is dupilumab use in atopic dermatitis associated with cutaneous T-cell lymphoma?. J Allergy Clin Immunol. 2025;155(5):1481-1482. doi:10.1016/j.jaci.2025.02.002

[164] Geskin LJ, Viragova S, Stolz DB, Fuschiotti P. Interleukin-13 is overexpressed in cutaneous T-cell lymphoma cells and regulates their proliferation. Blood. 2015;125(18):2798-2805. doi:10.1182/blood-2014-07-590398

shift, might promote T-cell clone emergence leading to CTCL development.[165] Researchers have also proposed that Dupixent may act as a trigger for the progression of initially benign lymphoid infiltrates leading to the clonal expansion of T lymphocytes and their subsequent malignant transformation.[166]

201. More recently, researchers performed single-cell sequencing on peripheral blood mononuclear cells sampled from an atopic dermatitis patient who developed CTCL with severe blood involvement after 3 months of Dupixent treatment.[167] These researchers subjected the peripheral blood mononuclear cells to treatment with IL-4 and IL-13, with and without Dupixent, to explore underlying mechanisms of Dupixent and its target cytokines in CTCL pathogenesis. Dupixent was observed to reduce IL-4 receptor expression and increase IL-13 receptor alpha 1 expression in corresponding cell types. Notably, researchers found that Dupixent treatment significantly increased the proliferation of tumorous T cells, and that those tumorous T cells exhibited a markedly higher gamma-delta T-cell aggressive score and upregulated exhaustion markers. Similarly, the interferon response pathway in cells, known to be associated with aggressiveness and poor prognosis in gamma-delta T-cell lymphoma, was enriched after Dupixent treatment. Furthermore, Dupixent was observed to upregulate several genes in monocytes that are known to promote tumor progression. Ultimately, these researchers determined their case served to provide "evidence that dupilumab promotes tumor progression in T cell lymphoma".

202. The aforementioned data, analyses and information described in this Complaint,

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[165] Beylot-Barry M, Staumont-Salle D. Cutaneous T-Cell Lymphoma and Dupilumab Use: A Multifactorial and Complex Story. J Invest Dermatol. 2025;145(1):9-11. doi:10.1016/j.jid.2024.08.015

[166] Sokumbi O, Shamim H, Davis MDP, Wetter DA, Newman CC, Comfere N. Evolution of Dupilumab-Associated Cutaneous Atypical Lymphoid Infiltrates. Am J Dermatopathol. 2021;43(10):714-720. doi:10.1097/DAD.0000000000001875

[167] Li M, Xiao Y, Jiang Y, Wang Y. 0912: Dupilumab unmasking cutaneous γδ T cell lymphoma through promoting tumorous T cell aggressiveness and microenvironment reprogramming. J Invest Dermatol. 2025;145(8):S158. doi:10.1016/j.jid.2025.06.928

including the case reports, case series, descriptive observational studies, analytic cohort studies, disproportionality analyses and postmarketing adverse events, that were received prior to Plaintiff's use of Dupixent constitutes newly acquired information pursuant to C.F.R. § 601.12 (f)(6), which supported a label change to Dupixent in order to properly warn about CTCL with Dupixent use.

G. Defendants' Reaction to Negative Research

203. In response to research identifying a strong causal connection between Dupixent and CTCL, Defendants did not express concern for patient safety or commit to taking necessary actions to protect patients and develop a better understanding of this relationship. Instead, Defendants launched an aggressive publishing campaign to assuage fears among patients and healthcare providers that might otherwise lead to a reduction in prescriptions for Dupixent. Defendants' employees, along with KOLs paid by Defendants, published original studies and wrote multiple letters to editors of journals that had published research concerning Dupixent and CTCL in order to sow doubt into the findings of these studies and to shape a narrative that would deflect attention from Dupixent and redirect blame for the observed CTCL risk to an alternative culprit: atopic dermatitis itself. Defendants also attempted to direct blame for CTCL to physicians and further suggested that many CTCL diagnoses in Dupixent-treated patients were actually a benign, reversible reaction and not CTCL.

204. Defendants' employees and Defendants' retained KOLs submitted two letters to the editor in response to the Hasan 2024 study, the first cohort study reporting a statistically significant increased risk of CTCL with Dupixent use.

205. The first letter was published on August 24, 2024 and co-authored by Yung-Tsu Cho, MD, PhD, who served as a sub-investigator for Defendants Sanofi-Aventis and Regeneron

and received speaker fees from Defendant Sanofi-Aventis, and Chia-Yu Chu, MD, PhD, who served as a sub-investigator for Defendants Sanofi-Aventis and Regeneron, served as a consultant/advisory board member for Defendant Sanofi-Aventis, and received speaker fees from Defendant Sanofi-Aventis.[168] In this short letter, these authors argued that the atopic dermatitis population experiences an increased rate of CTCL and other lymphomas irrespective of Dupixent use and suggested it was possible that some proportion of reported CTCL cases in the Hasan study may actually have been lymphoid reactions rather than CTCL. Interestingly, the two publications cited by Cho and Chu in support of their claim that atopic dermatitis patients experience an elevated rate of CTCL were each co-authored by KOLs retained by Defendants Sanofi-Aventis and Regeneron. They also made certain unfounded assumptions regarding the composition of the study groups without citing any data in support of their position, and ultimately advised fellow dermatologists to observe their patients for the development of certain adverse events rather than to exercise caution in prescribing Dupixent. Although no funding source was claimed, this letter was published according to Open Access at a price of $4,200.

206. The second letter was funded by Defendants Sanofi-Aventis and Regeneron and published on September 30, 2024.[169] This letter was co-authored by 10 employees of Defendants Sanofi-Aventis and Regeneron. After performing what they referred to as a thoughtful evaluation of the study by Hasan and colleagues, Defendants' employees proceeded to conclude the study was invalid and reached unsupported conclusions. In support of this position, Defendants' employees claimed that the atopic dermatitis population experiences an increased rate of CTCL,

[168] Cho YT, Chu CY. Response to Hasan et al., "Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T-cell lymphoma: A retrospective cohort study". J Am Acad Dermatol. 2025;92(1):e9-e10. doi:10.1016/j.jaad.2024.06.105

[169] Nguyen TV, Marcus AF, Sinnott SJ, et al. Commentary: Response to "Dupilumab therapy for atopic dermatitis is associated with increased risk of cutaneous T cell lymphoma: A retrospective cohort study". J Am Acad Dermatol. 2025;92(2):e41-e42. doi:10.1016/j.jaad.2024.08.082

citing the same KOL-authored study relied upon by Cho and Chu and another industry-funded study also co-authored by one of Defendants' KOLs. They also claimed that the comparator group in the Hasan study was inappropriate, based upon their belief that those not treated with Dupixent were more likely to have less severe disease. Relatedly, they further advanced the unfounded assumption that "dupilumab is generally prescribed to patients with chronic, refractory AD", which runs contrary to the clinical treatment guidelines their employers funded that recommend Dupixent as a first-line treatment and advocate for its use in otherwise treatment-naïve patients. Additionally, Defendants' employees expressly claimed that the European Medicines Agency (EMA) performed a review of CTCL in 2022 and determined "no causal association between dupilumab and CTCL can be established". However, no such conclusion appears in the cited EMA report. Finally, the authors stated "[a]s of March 28, 2024, ongoing safety surveillance activities for dupilumab have not identified an association with CTCL", and that "the available evidence does not support a causal association between dupilumab and CTCL".

207. Clearly, Defendants' employees took an untenable position as, upon information and belief, Defendants knew, or through the exercise of reasonable diligence should have known at the time this letter was first published that 4 retrospective cohort studies, 2 disproportionality analyses and no fewer than 20 case reports and case series encompassing dozens of patients had been published reporting an association between Dupixent and CTCL. This is in addition to the cases of CTCL observed during the Dupixent clinical development program, including the 3 cases reported in the long-term extension trial.

208. Defendants doubled down on their misrepresentations in a lengthy review of

Dupixent safety data published in September 2025.[170] This article was co-authored by 1 KOL (Richard G. Langley) and 10 employee-shareholders of Defendants. Although Defendants framed this review as being the "most comprehensive dupilumab safety assessment to date for the treatment of moderate-to-severe atopic dermatitis", they instead used it as an opportunity to publicly misrepresent clinical trial data and the safety profile of Dupixent. As an initial matter, Defendants selectively omitted important safety data from the review by focusing only on a subset of the clinical trials that had been completed in the atopic dermatitis development program. Despite substantial evidence of an association between Dupixent and CTCL from 6 retrospective cohort studies, 5 disproportionality analyses and dozens of descriptive cohort studies, case reports, case series and systematic reviews – in addition to being notified by the FDA that the agency had identified a safety signal for CTCL with Dupixent – Defendants boldly, and falsely – represented " [t]here is currently no evidence associating CTCL and dupilumab treatment". In alignment with their detraction playbook, Defendants then proceeded to blame atopic dermatitis for any reported CTCL risk, downplay the utility of spontaneous adverse event data analysis in postmarketing surveillance and discount any available research concerning Dupixent and CTCL, serially citing their own letter to the editor (Nguyen et al. 2025) and other pieces authored by company KOLs as support for their unsound position.

209. Taking it a step further, two KOLs retained by Defendants, Emma Guttman-Yassky, MD, PhD and Patrick M. Brunner, MD, in conjunction with others, submitted a research letter ("Neubauer 2024 research letter") in response to the Hasan 2024 study which was published on

[170] Langley RG, Gherardi G, Coleman A, et al. The Safety Data of Dupilumab for the Treatment of Moderate-to-Severe Atopic Dermatitis in Infants, Children, Adolescents, and Adults. Am J Clin Dermatol. 2025;26(6):981-1002. doi:10.1007/s40257-025-00952-w

September 7, 2024.[171] Despite expressly claiming no funding sources in the publication, these authors included several statements indicative of strong bias and industry influence. Examples include "[w]e are concerned that this report might negatively influence physicians from prescribing dupilumab, causing more harm than good" and "[a]pproval of dupilumab has been life-changing for AD patients. Concerns over CTCL should not sway dermatologists from utilizing dupilumab for AD, with skin biopsy indicated in equivocal cases." Of note, during a 24-month period beginning in 2023, Defendants compensated Emma Guttman-Yassky, MD, PhD $130,715 in general payments and $3,572 in research payments along with $1,920,394 in associated research funding according to CMS OpenPayments data. Patrick M. Brunner, MD likewise received $15,359 in general payments from Defendants during this period. Co-author Larisa J. Geskin, MD had also been paid $29,610 in consulting fees by Regeneron in 2021 for work related to Dupixent.

210. Just 12 days prior to the publication of the Neubauer 2024 research letter, Emma Guttman-Yassky, MD, PhD and her colleagues submitted yet another study investigating malignancies among atopic dermatitis patients treated with Dupixent.[172] Using data from TriNetX, these authors ultimately reported that Dupixent-treated patients had a significantly lower risk of internal malignancy development compared with patients treated with other atopic dermatitis therapies. Oddly, however, these authors claimed there were not enough cases in TriNetX to examine CTCL as a specific endpoint, while nonetheless postulating that patients with severe atopic dermatitis may have a higher baseline lymphoma risk regardless of treatment exposure. Their claim of an inadequate number of CTCL cases is peculiar for several reasons, particularly

[171] Neubauer ZJK, Brunner PM, Geskin LJ, Guttman E, Lipner SR. Decoupling the association of dupilumab with cutaneous T-cell lymphoma. J Am Acad Dermatol. 2024;91(6):1296-1298. doi:10.1016/j.jaad.2024.08.057

[172] Garate D, Thang CJ, Chang CT, et al. Risk of malignancy associated with use of dupilumab versus other treatments in atopic dermatitis patients: A national database analysis. J Allergy Clin Immunol Pract. 2025;13(3):698-701.e1. doi:10.1016/j.jaip.2024.11.015

given that Emma Guttman-Yassky, MD, PhD and colleagues had an adequate number of cases to analyze CTCL as an endpoint when conducting almost the same exact study, at almost the same exact time, in the same database, yet followed patients over a period four times shorter (20 years vs. 5 years) in the Neubauer 2024 research letter. Also curious, senior author Nicholas Gulati, MD, PhD declared no conflicts of interest in the publication despite receiving 31 payments from Regeneron and Sanofi-Aventis's wholly-owned subsidiary Genzyme Corporation in 2023 and 2024 according to CMS OpenPayments data.

211. One month after the publication of the Neubauer 2024 research letter, Patrick M. Brunner, MD, as senior author, submitted a review publication in which he self-cited his Neubauer research letter to bolster the perceived reliability and reach of the findings.[173] Brunner describes in detail the findings of the research letter, using the term "they" to refer to its authors in an attempt to manufacture some perception of independence from the current work. Additionally, the authors noted that none of the CTCL cases in the Lavin study reporting a safety signal for CTCL with Dupixent involved patients treated for non-cutaneous indications, suggesting atopic dermatitis was driving the apparent CTCL risk.

212. A February 13, 2025 editorial authored by Defendants' KOL Peck Y. Ong, MD sought downplay the safety signal for CTCL with Dupixent reported in the disproportionality analysis by Cabrera-Perez and colleagues.[174] In common refrain with other letters and editorials authored by Defendants' KOLs, Ong carefully noted the Cabrera-Perez et al. "observation that CTCL was reported almost exclusively in patients with AD, but not in those with asthma or other atopic conditions, suggests that dupilumab by itself is not causative of CTCL". Ong also advanced

[173] Meledathu S, Naidu MP, Brunner PM. Update on atopic dermatitis. J Allergy Clin Immunol. 2025;155(4):1124-1132. doi:10.1016/j.jaci.2025.01.013
[174] Ong PY. Is dupilumab use in atopic dermatitis associated with cutaneous T-cell lymphoma?. J Allergy Clin Immunol. 2025;155(5):1481-1482. doi:10.1016/j.jaci.2025.02.002

the theory that the CTCL cases in the Cabrera-Perez 2024 study may have actually been benign cutaneous lymphoid reactions that were misdiagnosed as CTCL, relying on another study authored by Defendants' KOLs in support of this proposition. Despite acknowledging the findings of Cabrera-Perez et al. "support a worsening of CTCL with dupilumab use", Ong boldly concluded "[t]here is no evidence that dupilumab causes or leads to the development of CTCL in AD".

213. Another letter to the editor authored by multiple KOLs retained by Defendants aiming to allay concerns regarding the safety signal for CTCL with Dupixent reported by Lavin and colleagues was published in June 2025.[175] These authors put forward an interesting theory that "[h]eightened vigilance around CTCL shortly after the introduction of dupilumab for AD, may have led to over-reporting by dermatologists", despite the absence of a warning regarding CTCL in the prescribing information for Dupixent or any communications from Defendants regarding a potential relationship between Dupixent and CTCL, in addition to the existence of the well-known phenomenon of significant underreporting of postmarketing adverse events. Although the disproportionality analysis by Lavin et al. covered a period during which Dupixent had been approved for 6 unique indications (5 indications other than atopic dermatitis) in the United States, the authors "suggest[ed] that comparison with drugs not commonly used for AD could be misleading". Again, consistent with previous letters and editorials authored by Defendants' KOLs, these authors commented "[n]one of the CTCL reports in this paper (or other literature) featured dupilumab for asthma", further noting that an "[a]nalysis of associations in such people would be useful, as a lack of signal would further support the association being with AD over drug". These authors additionally pronounced "reports of CTCL in patients with severe AD predate dupilumab

[175] James ML, Pink AE, Woolf RT, et al. Response to Lavin et al (2025)'s Paper: Cutaneous T-Cell Lymphoma after Dupilumab Use: A Real-World Pharmacovigilance Study of the FDA Adverse Event Reporting System. J Invest Dermatol. 2025;145(9):2325-2326. doi:10.1016/j.jid.2025.05.022

and large-scale population-based evidence supports an increased risk of lymphoma in severe AD". However, the only research they could find to support these claims included a 2020 cohort study which specifically excluded patients with CTCL and a small 2004 case series of 4 patients with long-term atopic dermatitis who eventually developed lymphomatoid papulosis or cutaneous anaplastic large cell lymphoma. Ultimately, Defendants' KOLs concluded, "[w]e highlight that no clear causal association has been identified".

214. Next, craftily circumventing the hassles and uncertainties of the peer review process, Defendants leaned on their deep connections with members of scientific journal editorial and advisory boards to dispel CTCL concerns and champion the continued, unfettered use of Dupixent.

215. In September 2025, in response to the study by Sheng-Kai Ma and colleagues identifying a strong, significant association between Dupixent use and CTCL among asthma patients, Defendants' KOL Ian D. Pavord, DM published an editorial.[176] Dr. Pavord, who is also a member of the advisory board of the publishing journal and a contributor to Defendants' ADVENT platform, acknowledged "dupilumab may be associated with an increased risk of cutaneous lymphoma", while downplaying the magnitude of the observed risk as "very small", asserting that cutaneous lymphomas are "rarely life-threatening" and ultimately characterizing the findings of Sheng-Kai Ma et al (2025) as "much ado about nothing".

216. In October 2025, Tiago Torres, a KOL retained by Sanofi-Aventis's wholly-owned subsidiary Genzyme Corporation, published an editorial in a journal for which he serves as an Editorial Board member, describing recent research concerning Dupixent and CTCL.[177] As with other pieces authored by Defendants and their KOLs, Dr. Torres casted Dupixent as having

[176] Davies TJ, Pavord ID. Lymphoma in patients with asthma treated with dupilumab: much ado about nothing?. Eur Respir J. 2025;66(3):2501321. Published 2025 Sep 25. doi:10.1183/13993003.01321-2025
[177] Torres T. Dupilumab and Cutaneous T-Cell Lymphoma: A Call for Vigilance, Not Alarm. Am J Clin Dermatol. Published online October 22, 2025. doi:10.1007/s40257-025-00991-3

"revolutionized" atopic dermatitis treatment while emphasizing that the risk of CTCL should not stop physicians from prescribing Dupixent, in triplicate, as follows: "overstating a malignancy risk could discourage clinicians from prescribing a highly effective and generally well-tolerated therapy, potentially depriving patients of substantial clinical benefit"; "concerns regarding CTCL in the context of dupilumab should not deter the use of a highly effective, safe, and well-tolerated therapy"; and "Does this mean dermatologists should be reluctant to prescribe dupilumab? Certainly not." Nonetheless, Dr. Torres did concede in his editorial that the "CTCL signal" for Dupixent was "potentially real" while also describing various biological mechanisms providing "a plausible link between dupilumab and CTCL risk".

217. Another Defendant-funded KOL and his colleagues argued against a causal link between Dupixent and CTCL in an editorial published in November 2025.[178] In their editorial, these authors repeatedly mischaracterized evidence concerning CTCL with Dupixent use, referred to findings from high quality epidemiologic studies and well-documented case series as "anecdotal", and concluded that available research did not provide "convincing evidence of causality". Despite acknowledging that causal mechanisms for Dupixent-induced CTCL that have been proposed in the literature "are plausible", the authors suggested atopic dermatitis was more likely responsible for the observed CTCL risk, and ultimately advocated, "we do not believe dupilumab use should be limited due to concern about CTCL risk, particularly given its efficacy in treating chronic inflammatory diseases". Curiously, while expressly declaring he "has no conflicts to disclose" in the disclosures section of this editorial, the senior author Adam Friedman, MD, FAAD has received over $850,000 in general payments from Defendants, including $519,143.97 from Sanofi-Aventis's subsidiary Genzyme Corporation and $349,501.37 from

[178] Farah M, Zarabian N, Friedman A. Connecting the Plaques: Exploring the Link Between Dupilumab and Cutaneous T-cell Lymphoma. J Drugs Dermatol. 2025;24(11):1148-1149. doi:10.36849/JDD.1125

Regeneron Healthcare Solutions, Inc., a subsidiary of Defendant Regeneron.

218. More recently, Defendants' efforts to manipulate the scientific record were exemplified in the Kridin 2026 study.[179] One of the co-authors of this study, Diamant Thaçi, is a consultant, speaker and/or advisory board member for Defendants. Additionally, the senior author of this study, Ralf J. Ludwig, is an editorial board member of the journal in which it was published. However, here the conflict of interest extended beyond authorship and editorial board connections. Independent, unbiased peer review is a hallmark of academic publishing and is vital to ensure that published scholarly work reflects an honest and reliable application of the scientific process to advance knowledge on a given research question. Peer review is an essential gatekeeping function that maintains trust in the scientific research enterprise and safeguards against the publication of unwarranted claims, unacceptable interpretations or personal views without impartial appraisal and verification by experts in the field. Despite this imperative, both of the peer reviewers charged with evaluating the rigor, integrity and veracity of this paper prior to its publication were Defendants' KOLs. The first peer reviewer was Patrick Brunner, Defendants' KOL and co-author of the Neubauer 2024 research letter, and the second peer reviewer was Filip Rob, who also serves as a paid KOL for Defendants.[180] Beyond design flaws and flouting scientific publishing conventions, other aspects of this publication are equally troubling. In their discussion section, the authors stated their findings were "in line with a recent report on no increased CTCL risk in AD patients", citing the Neubauer 2024 research letter co-authored by KOL – and now peer reviewer

[179] Kridin K, Bieber K, Olbrich H, von Bubnoff D, Hernandez G, Zirpel H, von Bubnoff N, Thaçi D, Ludwig RJ. Dupilumab treatment is not associated with changes in lymphoma risk in atopic dermatitis and other type 2 inflammatory diseases: data from a large-scale retrospective cohort study. Front Med. 2026;12:1702736. doi:10.3389/fmed.2025.1702736

[180] *See* "Disclosure statement" *in* Rob F, Pinkova B, Sokolova K, Kopuleta J, Jiraskova Zakostelska Z, Cadova J. Real-world efficacy and safety of dupilumab in children with atopic dermatitis under 6 years of age: a retrospective multicentric study. J Dermatolog Treat. 2025;36(1):2460578. doi:10.1080/09546634.2025.2460578

– Patrick Brunner. They then went on to state that their findings "seemingly contrast[ed] with two previous reports on this topic", citing only the Hasan 2024 study and the cross-sectional study by Hamp and colleagues. As a result, the authors framed the body of research concerning Dupixent and CTCL as consisting only of these four studies, with two finding an association and two finding no association. Such a discussion could hardly be considered balanced or accurately placing the present findings in appropriate context with extant research on the subject, and as such, this is something that unbiased peer reviewers would have demanded remedying prior to publication.

219. As reflected above, Defendants dedicated considerable time, effort and financial resources to shaping an elaborate narrative that would downplay the risk of CTCL with Dupixent through these publications. At no point did Defendants acknowledge the merits of the findings produced through independent research or take initiative to commit to conducting necessary studies to better understand the pathological mechanisms of Dupixent-induced CTCL or discover why Dupixent triggers rapid and severe progression of subclinical CTCL.

H. Defendants' Labeling and Instructions for Dupixent

220. From its original approval in 2017 to the present, the United States prescribing information for Dupixent has been deficient in that it has failed to provide adequate instructions for its safe prescription and use. At all times relevant hereto, the United States prescribing information for Dupixent has contained **1)** no BOXED WARNING advising patients and their healthcare providers of the risk of CTCL or any other form of cancer with Dupixent treatment; **2)** no warnings in section 5, WARNINGS AND PRECAUTIONS, advising patients and their healthcare providers of the risk of CTCL or any other form of cancer with Dupixent treatment; **3)** no reference to CTCL in section 6, ADVERSE REACTIONS, advising patients and their healthcare providers that clinically significant CTCL adverse reactions have been reported with

the use of Dupixent; **4)** no contraindication for use in patients with a history of CTCL or active CTCL; **5)** no instructions directing healthcare providers to perform adequate testing of patients (through biopsy or other means) to confirm a clinical diagnosis of atopic dermatitis, particularly in equivocal cases, before commencing treatment with Dupixent; **6)** no instructions directing healthcare providers to perform adequate testing of patients (through biopsy, cytometry or other means) to rule out the presence of subclinical or smoldering CTCL before commencing treatment with Dupixent; **7)** no instructions directing healthcare providers to perform regular and continuous monitoring during treatment with Dupixent for the development of signs and symptoms of CTCL and repeat biopsies to detect changes in pathologies during treatment with Dupixent consistent with CTCL development; and **8)** no instructions directing healthcare providers to discontinue use of Dupixent when a patient exhibits signs of non-responsiveness to treatment or worsening of disease, or otherwise develops signs and symptoms consistent with CTCL.

221. Defendants' failure to add the above-referenced information to the United States prescribing information for Dupixent is despite sufficient notice of reasonable evidence of a causal association between Dupixent use and incident CTCL that would have supported inclusion of this information well before Plaintiff's use of Dupixent.

222. Defendants' failure to appropriately revise the United States prescribing information for Dupixent to reflect the clinically important risk of CTCL with Dupixent treatment continued in the face of mounting evidence from dozens and dozens of postmarketing adverse events, published case reports, published case series, descriptive observational studies, analytic cohort studies and disproportionality analyses.

223. The vast body of scientific evidence discussed *supra* establishes that there exists a strong and consistent causal relationship between the use of Dupixent and incident CTCL, to

include both new cases of CTCL and rapid exacerbation of subclinical CTCL, which was known or knowable to Defendants at all times relevant hereto. Further, at all times relevant hereto, numerous practical measures to prevent, mitigate and/or reduce the risk of Dupixent-induced and Dupixent-exacerbated CTCL were known or knowable to Defendants.

224. At all times relevant hereto, Defendants maintained complete responsibility for the content of the United States Prescribing Information for Dupixent.

225. At all times relevant hereto, Defendants were under a duty to advise healthcare providers within Section 5, WARNINGS AND PRECAUTIONS of the United States Prescribing Information for Dupixent, of clinically significant adverse reactions associated with the use of Dupixent, including any that are potentially fatal, that are serious even if infrequent or that can be prevented or mitigated through appropriate use of the drug, along with limitations in use imposed by such reactions. (21 CFR 201.57(c)(6)(i)).

226. At all times relevant hereto, Defendants were under a duty to advise healthcare providers within Section 5, WARNINGS AND PRECAUTIONS of the United States Prescribing Information for Dupixent, of laboratory tests that should be performed before, during and after therapy to follow patient responses or identify possible adverse reactions associated with the use of Dupixent. (21 CFR 201.57(c)(6)(iii)).

227. At all times relevant hereto, Defendants were under a duty to advise healthcare providers within a BOXED WARNING in the United States Prescribing Information for Dupixent, of clinically significant adverse reactions, particularly those that may lead to death or serious injury, associated with the use of Dupixent. (21 CFR 201.57(c)(1)).

228. At all times relevant hereto, Defendants were under a duty to promptly revise the United States Prescribing Information for Dupixent to add warnings regarding clinically

significant hazards as soon as there is reasonable evidence of a causal association with the drug. (21 CFR 201.57(c)(6)(i)). Importantly, however, a causal relationship need not have been definitely established in order to add such a warning to the United States Prescribing Information.

229. At all times relevant hereto, through submitting to the FDA a Changes Being Effected (CBE) Supplement, Defendants had available to them the option to unilaterally add new warnings regarding the risk of CTCL development, acceleration and exacerbation to the United States Prescribing Information for Dupixent reflecting newly-acquired information during the postmarketing period evidencing this clinically significant risk. (21 CFR 314.70(c)).

230. Similarly, through submitting a CBE Supplement to the FDA, Defendants had available to them the option to add new contraindications for use of Dupixent in patients without histopathologically confirmed atopic dermatitis or at risk of developing or experiencing exacerbation of subclinical CTCL and/or to add or strengthen instructions concerning dosage and administration of Dupixent that would serve to increase the safety of its use. (21 CFR 314.70(c))

231. Notwithstanding, Defendants chose not to undertake any such actions.

232. Further, at all times relevant hereto, Defendants failed to take other reasonable and prudent steps within their capacity, including, but not limited to sending "Dear Healthcare Provider" (DHCP) letters or issuing and disseminating safety alerts, to advise patients and healthcare providers that Dupixent treatment carries a significant risk of CTCL development and/or exacerbation and to convey appropriate mitigation strategies to reduce or eliminate the risk of Dupixent-induced and Dupixent-exacerbated CTCL. Similarly, Defendants failed to advise patients and healthcare providers of new research evidencing a significant risk of CTCL with Dupixent use through prudent and reasonable means within their capacity.

I. FDA Identifies Safety Signal for CTCL with Dupixent

233. On January 15, 2025, the FDA notified Defendant Regeneron via email that it identified and began evaluating a newly identified safety signal (NISS) regarding "dupilumab therapy for atopic dermatitis being associated with increased risk of cutaneous T cell lymphoma" on December 26, 2024. The FDA further noted that the agency had classified this NISS as a potential risk and that it was informing Regeneron Pharmaceuticals, Inc. in accordance with the Food and Drug Administration Amendments Act of 2007, the Food Drug & Cosmetic Act and their implementing regulations.[181,182]

234. On March 31, 2025, the FDA published its quarterly report "Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS)" for the 4th quarter of 2024.[183] In this report, FDA identified CTCL as a potential signal of a serious risk associated with Dupixent, and noted it was "evaluating the need for regulatory action".

235. As of the filing of this complaint, Defendants have still failed to implement appropriate labeling revisions to add necessary information regarding the risk of CTCL development or exacerbation with Dupixent use or appropriate mitigation strategies to reduce or eliminate the risk of Dupixent-induced and Dupixent-exacerbated CTCL.

236. Defendants' ongoing failure to warn, misrepresentations, and omissions, as set forth

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[181] Center for Drug Evaluation and Research. Manual of Policies and Procedures: MAPP 6700.9: FDA Posting of Potential Signals of Serious Risks Identified by the FDA Adverse Event Reporting System. U.S. Food and Drug Administration. September 9, 2019.
[182] Center for Biologics Evaluation and Research. Standard Operating Procedures and Policies: SOPP 8420: FDAAA Section 921: Posting of Potential Signals of Serious Risk. U.S. Food and Drug Administration. February 27, 2022.
[183] October - December 2024 | Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS). U.S. Food and Drug Administration. March 31, 2025. https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/october-december-2024-potential-signals-serious-risksnew-safety-information-identified-fda-adverse

supra, regarding the safety of Dupixent and the risks of development or aggravation of CTCL from same constitute a continuing tort.

FACTS SPECIFIC TO PLAINTIFF

237. Plaintiff William Douglas developed a skin rash as an adult. The rash was diagnosed and treated as eczematous dermatitis.

238. In January 2025 Plaintiff was prescribed Dupixent to treat his eczematous dermatitis.

239. Plaintiff and Plaintiff's physicians used Dupixent in the manner in which it was intended and recommended to be used and did not misuse or alter Dupixent in an unforeseeable manner, making such use reasonably foreseeable to Defendants.

240. At all relevant times, Defendants represented Dupixent to be appropriate, safe and suitable for the purposes for which it was prescribed to Plaintiff.

241. Plaintiff used Dupixent from approximately January 2025 until September 2025. Plaintiff received multiple injections of Dupixent for approximately eight months and was repeatedly exposed to the drug.

242. Dupixent did not improve Plaintiff's condition.

243. Plaintiff had not been diagnosed with lymphoma of any kind prior to initiation of Dupixent.

244. Defendants manufactured, marketed and distributed the Dupixent that was injected into Plaintiff.

245. In or about September 2025 Plaintiff was diagnosed with mycosis fungoides, a form of CTCL. Plaintiff has been informed by his healthcare providers that his disease is at least Stage IB. Plaintiff's treatment has included phototherapy and Targretin.

246. Plaintiff has been advised by his healthcare providers that he will likely require ongoing treatments and healthcare services for CTCL indefinitely.

247. Before prescribing and using Dupixent, Plaintiff and, upon information and belief, Plaintiff's healthcare providers were exposed to Defendants' branded marketing for Dupixent and unbranded disease state awareness through television commercials.

248. But for Defendants' failure to provide a clear warning regarding the increased risk of CTCL development, exacerbation and progression with the use of Dupixent, Plaintiff's physician would not have prescribed him Dupixent and Plaintiff would not have taken Dupixent. Or at a minimum, Plaintiff's physician would have warned of the risk and Plaintiff would have declined Dupixent.

249. Defendants failed to timely and adequately warn Plaintiff and his medical providers of the propensity of Dupixent to cause the development and/or accelerate the progression of CTCL in individuals like Plaintiff who present with atypical, treatment-resistant and/or adult-onset eczema/dermatitis. Defendants failed to warn Plaintiff and his medical providers that for individuals like Plaintiff, appropriate diagnostic tests should be performed before initiating Dupixent treatment and during such treatment. Defendants also failed to warn Plaintiff and his medical providers to cease use of Dupixent and/or to get appropriate diagnostic tests to diagnose or rule out CTCL if Dupixent did not improve his condition, if his skin condition became worse while on Dupixent, or if he developed lymphadenopathy. Upon information and belief, had Defendants provided such warnings and instructions, Plaintiff's healthcare providers would not have prescribed him Dupixent and/or Plaintiff would not have taken Dupixent even if prescribed, or, at a minimum, Plaintiff would have been taken off of or ceased using the drug earlier.

250. Defendants' failure to warn resulted in Plaintiff being diagnosed with and/or the

accelerated progression of CTCL.

251. At the time Plaintiff was first prescribed Dupixent, the available scientific data were adequate to put Defendants on notice that there existed reasonable evidence of causal association between Dupixent and development and progression of CTCL.

252. Throughout the relevant period, Plaintiff exercised reasonable diligence by seeking medical care, undergoing diagnostic testing, and following the advice of his treating physicians.

253. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and Plaintiff's medical providers the true and significant risks associated with Dupixent and the causal connection between Dupixent and CTCL.

254. As a direct and proximate result of the Defendants' wrongful actions and inactions and the dangerous and defective nature of Dupixent as described herein, Plaintiff suffered severe bodily injury, and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity for the enjoyment of life, and expense of hospitalization and treatment. The losses are permanent and Plaintiff will continue to suffer the losses in the future.

COUNT I
STRICT LIABILITY – FAILURE TO WARN
N.J. Stat. § 2A:58C-2; Tenn. Code Ann. § 29-28-101 *et seq.*

255. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

256. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Dupixent and placed Dupixent into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

257. Defendants as the holder of the Biologics License Application(s) and the marketers of the medication are responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

258. Defendants, as manufacturers, distributors, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Dupixent were inadequate.

259. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information or data was communicated to Plaintiff or to Plaintiff's prescribing and treating physicians. Defendants had no reason to believe that Plaintiff or his prescribing and treating physicians would realize the risks of CTCL development or exacerbation from Dupixent use.

260. Defendants had a duty to provide adequate warnings and instructions for Dupixent, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their products.

261. Defendants had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Dupixent, as it became or could have become available to Defendants.

262. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Dupixent, to health care providers empowered to prescribe and dispense Dupixent to consumers, including Plaintiff, without adequate warnings and other

clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled and continue to mislead the medical community about the risk and benefit balance of Dupixent, which resulted in permanent injuries to Plaintiff.

263. Defendants knew or should have known through testing, scientific knowledge, advances in the field, or otherwise, that Dupixent created a risk of developing CTCL and/or triggering a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

264. Despite the fact that Defendants knew or should have known that Dupixent caused CTCL or rapidly accelerated subclinical CTCL, they continued to promote and market Dupixent without providing adequate clinically relevant information including recommending that when appropriate, at least one biopsy should be performed on the atopic dermatitis before administering Dupixent, and that monitoring for CTCL should be vigilantly performed and its use discontinued if symptoms appear.

265. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

266. The Dupixent supplied to Plaintiff by Defendants was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold. Defendants possessed knowledge and information confirming the defective and unreasonably dangerous nature of Dupixent, but despite this knowledge and information, Defendants failed and neglected to issue adequate warnings that Dupixent causes CTCL, and/or exacerbates subclinical CTCL and/or rapidly accelerates CTCL, and Defendants have yet to issue any warnings or recommendations that patients taking Dupixent undergo monitoring.

267. Defendants' failure to provide adequate warnings and instructions rendered

Dupixent unreasonably dangerous in that Dupixent failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by the Defendants, and in that the risk of danger outweighs the benefits.

268. Defendants continue to fail to provide adequate warnings to physicians, pharmacies, and consumers.

269. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Dupixent including CTCL.

270. Defendants failed to provide adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of, among other things, CTCL.

271. Defendants continued to aggressively promote and sell Dupixent, overstating its benefits and neglecting to warn of the risks of CTCL even after they knew or should have known of the unreasonable risks of CTCL.

272. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Dupixent, of the need to monitor and biopsy the development of concerning lesions and/or that there existed safer and/or equally effective alternative drug products that do not pose this same risk.

273. By failing to adequately test and research harms associated with Dupixent, and by failing to provide appropriate warnings and instructions about use, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Dupixent and were not aware of the serious risks of CTCL development, exacerbation and rapid progression associated with use of Dupixent. Nor were the medical community, patients,

patients' families, or regulators appropriately informed that CTCL development, exacerbation and progression might be a side effect of Dupixent and should or could be reported as an adverse event.

274. The Dupixent designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks of CTCL from using Dupixent, Defendants failed to provide adequate warnings to physicians, users or consumers, and continued to improperly advertise, market and/or overly promote.

275. Dupixent is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendants had exercised all possible care in their preparation and sale.

276. The risk of CTCL caused by Dupixent could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers had Defendants provided reasonable instructions and warnings of these foreseeable risks of harm.

277. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, lack of information, lack of adequate testing and research, and the defective and dangerous nature of Dupixent, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT II
STRICT LIABILITY – DESIGN DEFECT
N.J. Stat. § 2A:58C-2; Tenn. Code Ann. § 29-28-101 *et seq.*

278. Plaintiff incorporates by reference each and every preceding paragraph as if fully

set forth herein.

279. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Dupixent and placed Dupixent into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

280. Defendants as the holder of Biologics License Application(s) are responsible for communications to the FDA and associated regulatory authorities, reporting adverse events, label changes, post-market surveillance and pharmacovigilance.

281. Defendants, as manufacturers, designers, distributers, and marketers of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

282. Dupixent was designed in such a way that it posed an unreasonable risk of CTCL development, acceleration and rapid progression and was kept on the market despite being in a defective condition.

283. Defendants knew or should have known the Dupixent they developed, manufactured, labeled, marketed, sold, and/or promoted was defectively designed in that it posed a serious risk of CTCL development, acceleration and rapid progression.

284. Defendants had a continuing duty to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor their product.

285. Defendants sold, marketed and distributed products that are unreasonably dangerous for their normal, intended, and foreseeable use.

286. Defendants designed, researched, manufactured, tested, advertised, promoted,

marketed, sold and distributed Dupixent, a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

287. The Dupixent supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants, posing a risk of serious and potentially fatal CTCL to Plaintiff and other consumers.

288. The Dupixent taken by Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

289. The Dupixent taken by Plaintiff was in a condition not contemplated by Plaintiff in that it was unreasonably dangerous, posing a serious risk of CTCL development, acceleration and rapid progression.

290. Dupixent is a medication indicated for treatment of eczema, also known as atopic dermatitis. Dupixent in fact causes and/or triggers a reaction leading to severe and rapid clinical progression and exacerbation of otherwise subclinical and undiagnosed CTCL.

291. Plaintiff, ordinary consumers, and prescribers would not expect a drug designed, marketed, and labeled for treatment of atopic dermatitis and marketed for all of its supposed health benefits to cause CTCL development, acceleration and rapid progression.

292. The Dupixent supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially fatal CTCL to Plaintiff and other consumers.

293. The Dupixent supplied to Plaintiff by Defendants was defective in design or formulation in that its alleged benefits did not outweigh the risks of serious and potentially fatal CTCL posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of Dupixent makes the product unreasonably dangerous.

294. Dupixent's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

295. The intended or actual utility of Dupixent is not of such benefit to justify the risk of CTCL, rendering the product unreasonably dangerous.

296. The design defects render Dupixent more dangerous than other drugs and therapies designed for treatment of eczema and atopic dermatitis and cause an unreasonable increased risk of injury.

297. Defendants knew or should have known through testing, scientific knowledge, advances in the field, or otherwise, that Dupixent created a risk of CTCL development, acceleration and rapid progression.

298. Dupixent is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite knowledge that Dupixent could result in CTCL development, acceleration and rapid progression, Defendants failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its carcinogenic effects, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

299. Defendants acted unreasonably in their design of Dupixent in that Defendants failed to adopt a safer design for the product that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of

harm without substantially impairing the usefulness, practicality, or desirability of the product.

300. Defendants knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Dupixent's defective design.

301. Dupixent is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendants had exercised all possible care in the preparation and sale of these products.

302. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Dupixent, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT III
NEGLIGENCE
Tennessee Common Law & Tenn. Code Ann. § 29-28-101 *et seq.*

303. Plaintiff incorporates by reference each and every preceding paragraph as if fully set forth herein.

304. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, distributing, and/or promoting Dupixent for use by consumers, such as Plaintiff.

305. At all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, formulation, manufacture, labeling, promotion, advertisement, marketing, distribution, and sale of Dupixent for use by consumers, such as Plaintiff, to ensure that

use of Dupixent did not result in avoidable injuries.

306. At all times relevant to this action, Defendants owed a duty to consumers, physicians, and the general public to assess, manage, and communicate the risks, dangers, and adverse effects of Dupixent, and to warn consumers and the medical community, including Plaintiff and Plaintiff's prescribing and treating physicians, of those risks, dangers, and adverse effects.

307. Defendants' duties include, but are not limited to, carefully and properly advertising, analyzing, designing, developing, distributing, formulating, labeling, manufacturing, marketing, promoting, researching, selling, and testing Dupixent, which was placed in the stream of commerce, and providing adequate information regarding the appropriate use of Dupixent.

308. Prior to and during the time frame of Plaintiff's use of Dupixent, Defendants breached these duties, failed to exercise reasonable care, and were grossly negligent and careless in the testing, study, research, manufacture, labeling, promotion, advertisement, marketing, distribution, and sale of Dupixent.

309. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with Dupixent.

310. Defendants had access to clinical trial and registry data and were aware of complaints that Dupixent caused serious complications including but not limited to the development, exacerbation and acceleration of CTCL.

311. Despite the fact that Defendants knew or should have known that Dupixent posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the drug without revising any warning language.

312. Defendants breached the above-described duties to Plaintiff and failed to exercise due care under the circumstances causing Plaintiff injury, and Defendants' negligence, gross negligence and recklessness includes the following acts and omissions:

a. Failing in their obligation to provide consumers and the medical community, including Plaintiff and Plaintiff's prescribing and treating physicians, with accurate, adequate and clinically relevant information, data and warnings regarding the risk of CTCL associated with use of Dupixent, and/or that there existed safer alternative pharmaceutical drugs to treat Plaintiff's condition(s);

b. Failing to properly and adequately test Dupixent before releasing the drug to market;

c. Failing to continually monitor, test, and analyze data regarding safety, efficacy, and the prescribing practices for Dupixent;

d. failing to conduct adequate post-marketing studies, non-clinical and clinical testing, and post-marketing surveillance and analyses to determine and subsequently communicate the safety profile and side effects associated with the use of Dupixent;

e. Negligently manufacturing, marketing, advertising, distributing, and selling the drug;

f. Continuing to negligently manufacture and distribute the drug without adequate warnings and instructions after the Defendants knew or should have known of Dupixent's adverse effects;

g. Negligently manufacturing, marketing, advertising, distributing, and selling the drug to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the drug;

h. Failing to notify and warn the public and the medical community, including Plaintiff and Plaintiff's prescribing and treating physicians, of reported adverse drug events involving CTCL;

i. Failing to conduct sufficient clinical analysis of Dupixent, which if properly performed would have shown that Dupixent had serious side effects, including but not limited to the increased risks of the development or acceleration of CTCL;

j. Failing to conduct adequate pharmacovigilance and prepare a pharmacovigilance assessment and plan to mitigate the risks of the development or exacerbation of CTCL;

k. Misrepresenting the safety of Dupixent in labeling, advertising, package inserts,

promotional materials and other marketing resources and materials including but not limited to making claims of safety which misleadingly implied that Dupixent had been adequately evaluated for its carcinogenic potential;

l. Failing to provide warnings, instructions or other safety information that accurately reflected the risks of Dupixent and how to avoid same, including but not limited to the following:

i. failure to include a BOXED WARNING advising patients and their healthcare providers of the risk of CTCL with Dupixent treatment;
ii. failure to include warnings in section 5, WARNINGS AND PRECAUTIONS, advising patients and their healthcare providers of the risk of CTCL with Dupixent treatment;
iii. failure to reference to CTCL in section 6, ADVERSE REACTIONS, advising patients and their healthcare providers that clinically significant T-cell lymphoma adverse reactions have been reported with the use of Dupixent;
iv. failure to include a contraindication for use in patients with a history of CTCL or active T-cell lymphoma, including CTCL;
v. failure to include instructions directing healthcare providers to perform adequate testing of patients (through biopsy, cytometry or other means) to rule out the presence of subclinical or smoldering T-cell lymphoma before commencing treatment with Dupixent, especially for patients with presentations similar to Plaintiff (atypical, treatment-resistant and/or adult-onset dermatitis);
vi. failure to include instructions directing healthcare providers to perform regular and continuous monitoring during treatment with Dupixent for the development of signs and symptoms of CTCL and repeat biopsies to detect changes in pathologies during treatment with Dupixent consistent with CTCL development, especially for patients with presentations similar to Plaintiff (atypical, treatment-resistant and/or adult-onset dermatitis); and
vii. failure to include instructions directing healthcare providers to discontinue use of Dupixent when a patient exhibits signs of non-responsiveness to treatment or worsening of disease, or otherwise develops signs and symptoms consistent with CTCL.

m. Failing to provide adequate post-marketing warnings and instructions after

Defendants knew or should have known of the significant risks of serious adverse events and/or reactions, including, but not limited to an increased risk of CTCL associated with use of Dupixent;

n. Failing to exercise ordinary care in the advertisement and promotion of Dupixent;

o. Disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the serious risks of Dupixent;

p. Failing to adequately warn Plaintiff's prescribing and treating physicians regarding the increased risks of the development and acceleration of CTCL through various communication vehicles, including Dupixent's labeling, patient medication guides, Dear Healthcare Provider letters, press releases, and other risk communication options;

q. Aggressively and recklessly promoting Dupixent without adequate warnings and instructions even after Defendants knew or should have known of the unreasonable risks from the drug;

r. Downplaying, diminishing or hiding the risks associated with Dupixent, even after Defendants knew or should have known of the significant risks of Dupixent use; and

s. Violating applicable state and federal laws and regulations.

313. A reasonably prudent drug manufacturer, distributor, promoter, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

314. Defendants had a post-sale duty to warn physicians, including Plaintiff's prescribing and treating physicians, and consumers, including Plaintiff, about the potential risks and complications associated with use of Dupixent.

315. Plaintiff and Plaintiff's prescribing and treating physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Had Plaintiff and Plaintiff's prescribing and treating physicians received adequate warnings regarding the risks of Dupixent, Plaintiff would not have been prescribed and used the product or would have discontinued use at an earlier date.

316. Defendants knew and/or should have known that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the testing, labeling, supplying, marketing, selling, advertising, and warning of the risks and dangers of Dupixent, as described herein.

317. As a direct and proximate result of one or more of the above-stated acts, omissions, and conduct committed by the Defendants, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT IV
NEGLIGENCT MISREPRESENTATION
Tennessee Common Law & Tenn. Code Ann. § 29-28-101 *et seq.*

318. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

319. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Dupixent for use by consumers, such as Plaintiff.

320. Defendants owed a duty to prescribing physicians, other healthcare providers and to consumers of Dupixent, including Plaintiff, to accurately and truthfully represent the risks of the drug. Defendants breached their duty by misrepresenting the safety and known risks of Dupixent and/or by failing to adequately warn Plaintiff's prescribing and treating physicians, the medical

community, Plaintiff, and the public about the risks of Dupixent, including that use of Dupixent results in increased risk of the development, acceleration and exacerbation of CTCL in individuals with presentations similar to Plaintiff, which Defendants knew or in the exercise of diligence should have known.

321. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Dupixent knew, or reasonably should have known, that health care professionals and consumers of Dupixent would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing and using the drug.

322. The Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Dupixent knew, or reasonably should have known, that patients using Dupixent would suffer from the development, acceleration and exacerbation of CTCL because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff and Plaintiff's prescribing and treating physicians, was materially inaccurate, misleading, or otherwise false.

323. The Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the risks of Dupixent was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers, including via advertising campaigns, labeling materials, print advertisements, social media and commercial media, that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

324. Among Defendants' numerous misrepresentations and misleading omissions were Defendants' assurances that Dupixent was safe and effective, that it would "heal your skin from

within," that it would allow patients to "du [sic] more," and that it would provide "benefits with every breath."

325. Despite their knowledge of serious problems with Dupixent, Defendants continued to market Dupixent, present at conferences, and distribute medical literature, studies, and other communications to the medical community in an effort to mislead them and the general public about the risks associated with Dupixent and instead create the image and impression that Dupixent was safe for all patients.

326. Defendants made such statements even after they became aware of serious complications with Dupixent. Defendants did not reveal (and instead concealed) their knowledge of serious complications and other bad data.

327. Defendants made these representations with the intent to induce reliance thereon, and to encourage prescribing and using Dupixent.

328. Defendants knew or should have known that Plaintiff, Plaintiff's prescribing and treating physicians, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

329. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's prescribing and treating physicians were induced to, and did, prescribe and use Dupixent, thereby causing Plaintiff to suffer severe personal injuries.

330. Plaintiff and Plaintiff's prescribing and treating physicians would not have used or prescribed Dupixent had the true facts not been concealed by the Defendants.

331. Defendants had sole access to many of the material facts concerning the defective nature of Dupixent and its propensity to cause serious and dangerous side effects.

332. At the time Plaintiff was prescribed and took Dupixent, Plaintiff and Plaintiff's prescribing and treating physicians were unaware of Defendants' negligent misrepresentations and omissions.

333. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

334. Defendants failed to exercise ordinary care in making their representations concerning Dupixent.

335. Plaintiff and Plaintiff's prescribing and treating physicians reasonably relied upon the misrepresentations and omissions made by the Defendants.

336. Plaintiff's and Plaintiff's prescribing and treating physicians' reliance on the above-described misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

337. As a direct and proximate result of reliance upon Defendants' negligent misrepresentations and omissions, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT V
BREACH OF EXPRESS WARRANTY
N.J. Stat. Ann. § 12A:2-101 *et seq.*, Tennessee Common Law & Tenn. Code Ann. § 29-28-101 *et seq.*

338. Plaintiff incorporates by reference each and every preceding paragraph as though

fully set forth herein.

339. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Dupixent, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

340. Defendants as the holder of the Biologics License Application(s) are responsible for communications to the FDA and associated regulatory authorities, reporting of adverse events, label changes, post-market surveillance and pharmacovigilance.

341. Defendants expressly warranted to Plaintiff, Plaintiff's healthcare providers, and the general public, by and through Defendants and/or their authorized agents or sales representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that Dupixent was safe, effective, fit and proper for its intended use.

342. Dupixent materially failed to conform to those representations made by Defendants, in package inserts and otherwise, concerning the properties and effects of Dupixent, which Plaintiff purchased and injected in direct or indirect reliance upon these express representations. Such failures by Defendants constitute a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Dupixent sold to Plaintiff.

343. Defendants expressly warranted that Dupixent was safe and well-tolerated. However, Defendants did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Dupixent causes and/or triggers a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

344. Dupixent does not conform to those express representations because Dupixent is defective, not safe, and has serious adverse side effects.

345. Plaintiff and Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of Dupixent, and Defendants' representations became part of the basis of the bargain.

346. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' representations that Dupixent was safe and well-tolerated in their decision to ultimately prescribe, purchase and use the drug.

347. Plaintiff's healthcare providers justifiably relied on Defendants' representations through Defendants' marketing and sales representatives in deciding to prescribe Dupixent over other alternative treatments on the market, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

348. Plaintiff purchased and used Dupixent without knowing that the drug is not safe and well-tolerated, but that Dupixent instead causes CTCL and/or triggers a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

349. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, lack of adequate testing and research, and the defective and dangerous nature of Dupixent, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT VI
BREACH OF IMPLIED WARRANTY
Tennessee Common Law & Tenn. Code Ann. § 29-28-101 *et seq.*

350. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

351. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Dupixent, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

352. Defendants were the sellers of Dupixent and sold Dupixent to be taken for treatment of eczema and atopic dermatitis. Plaintiff was prescribed and purchased Dupixent for its intended purpose.

353. When the Dupixent was prescribed by Plaintiff's prescribing and treating physicians and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

354. Defendants impliedly warranted, through their marketing, advertising, distributors and sales representatives, that Dupixent was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

355. In fact, Dupixent was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

356. The Dupixent manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the drug to not cause the development, acceleration or

exacerbation of CTCL.

357. Plaintiff and Plaintiff's prescribing and treating physicians reasonably and justifiably relied upon the skill and judgment of Defendants as to whether Dupixent was of merchantable quality and safe for its intended and particular use and purpose.

358. Contrary to such implied warranties, Dupixent was not of merchantable quality or safe for its intended and particular use and purpose, because the drug causes the development, acceleration and exacerbation of CTCL.

359. Defendants' breach of their implied warranties resulted in Plaintiff being prescribed and using Dupixent, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

360. As a direct and proximate result of Defendants' conduct, including breach of implied warranties, Plaintiff suffered bodily injuries and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

COUNT VII
CONSUMER FRAUD ACT
N.J.S.A. 56:8 *et seq.*

361. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

362. Plaintiff purchased and used Dupixent primarily for personal use and therefore suffered ascertainable losses as a result of Defendants' actions in violation of N.J.S.A. 56:8 *et seq*.

363. Had Defendants not made affirmative misrepresentations, material omissions, and engaged in the deceptive conduct described herein, Plaintiff would not have purchased Dupixent and would not have incurred damages.

364. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

365. Despite knowing the falsity and misleading nature of their claims, Defendants engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment, suppression or omission of material facts relative to the safety and efficacy of Dupixent.

366. Defendants intended such actions to mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Dupixent.

367. Such actions did, in fact, mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Dupixent.

368. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Dupixent.

369. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of N.J.S.A. 56:8 *et seq*.

370. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Dupixent, Plaintiff suffered financial loss by purchasing Dupixent.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against

Defendants, as contained in the Prayer for Relief.

COUNT VIII
PUNITIVE DAMAGES
N.J.S.A. 2A:15-5.9, et seq.; Tennessee Common Law

371. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

372. Defendants have engaged in aggressive and reckless marketing efforts, including highlighting the lack of a requirement for initial laboratory testing and ongoing laboratory monitoring as a favorable attribute of Dupixent in promotional materials to physicians and patients despite the fact that such testing was necessary to avoid serious adverse health outcomes, such as Plaintiff's CTCL, and this was known or knowable to Defendants.

373. Defendants have engaged in marketing efforts seeking to induce healthcare providers to switch their patients from other medications to Dupixent despite lacking the necessary evidence to demonstrate that Dupixent is safe and effective in the adult-onset atopic dermatitis population and despite affirmative evidence that the drug is not safe in this patient population.

374. Defendants have engaged in marketing efforts seeking to induce healthcare providers to prescribe Dupixent to their patients without first obtaining diagnostic confirmation of an underlying indicated health condition.

375. Defendants have engaged in marketing efforts seeking to induce patients to specifically request a prescription of Dupixent from their healthcare provider when its use is not necessary or appropriate.

376. Defendants have intentionally misled healthcare providers and the general public in making superiority claims for Dupixent as compared to other medications despite possessing the knowledge that these claims are false.

377. Defendants have intentionally failed to properly warn healthcare providers about the true risk of CTCL related to Dupixent use despite possessing knowledge that Dupixent causes these serious adverse events.

378. The acts and omissions of Defendants described herein consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

379. Defendants' actions amounted to actual malice or reckless indifference to the likelihood of harm associated with their acts and omissions.

380. Defendants misled both the medical community and the public, including Plaintiff and his physicians, by making false representations about the safety and effectiveness of Dupixent and by failing to provide adequate instructions concerning its use.

381. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Dupixent despite available information demonstrating that the drug could cause CTCL, or trigger a reaction leading to severe and rapid clinical progression of otherwise subclinical and undiagnosed CTCL.

382. Defendants were or should have been in possession of evidence demonstrating that Dupixent use could cause, trigger, exacerbate and/or accelerate CTCL. Nevertheless, Defendants continue to market Dupixent by providing false and misleading information with regard to its safety and effectiveness.

383. Defendants failed to provide warnings that would have dissuaded health care professionals from using Dupixent, thus preventing health care professionals, including Plaintiff's prescribing and treating physicians, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Dupixent.

384. As a proximate result of Defendants' acts and omissions, Plaintiff was diagnosed with CTCL and/or his CTCL has been exacerbated and accelerated.

385. As a result of Plaintiff's injuries, Plaintiff has endured and will endure substantial pain and suffering, has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

386. Plaintiff has suffered and will continue to suffer economic loss and has otherwise been emotionally and economically injured.

387. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

388. The above-described acts or omissions of Defendants were actuated by actual malice or accompanied by a wanton and willful disregard of their customers who foreseeably might be harmed by those acts or omissions.

389. Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

390. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

391. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

WHEREFORE, Plaintiff respectfully requests that Plaintiff be granted relief against Defendants, as contained in the Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. For general damages in an amount to be proven at the time of trial;

b. For special damages in an amount to be proven at the time of trial;

c. For exemplary and punitive damages in an amount to be proven at trial, and sufficient to punish Defendants or to deter Defendants from repeating the injurious conduct alleged herein;

d. For the Consumer Fraud Act, refund of money, treble damages and attorney fees;

e. For pre-judgment and post-judgment interest on the above general and special damages;

f. For costs of this suit and attorneys' fees; and

g. All other relief, both legal and equitable, that this Court deems necessary, proper, and just.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues.

CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned attorney for Plaintiff certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;

2. No other action or arbitration proceeding is contemplated; and

3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of their action that should be joined pursuant to R. 4:28.

I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

CERTIFICATION PURSUANT TO RULE 4:5-1

Plaintiff certifies that the matter in controversy is not the subject of any other pending action in any court or of any pending arbitration proceeding, to the best of Plaintiff's knowledge and belief. Plaintiff further certifies that no other parties should be joined in this action at this time. Plaintiff is aware of the continuing obligation to file and serve an amended certification if there is a change in the facts stated herein.

DESIGNATION OF TRIAL COUNSEL PURSUANT TO RULE 4:25-4

Plaintiff designates as trial counsel, Ellen Relkin.

Dated: June 11, 2026

Respectfully submitted,

By: */s/ Ellen Relkin*

Ellen Relkin (Attorney ID # 006691985)
Laura J. Baughman (pro hac vice application forthcoming)
WEITZ & LUXENBERG, P.C.
220 Lake Drive East, Suite 210
Cherry Hill, New Jersey 08002
Phone: 856-755-1115
Fax: 856-755-1995
erelkin@weitzlux.com

Attorneys for Plaintiff

Civil Case Information Statement

Case Details: ATLANTIC | Civil Part Docket# L-001199-26

Case Caption: DOUGLAS WILLIAM VS SANOFI-AVENTIS U.S. LLC
Case Initiation Date: 06/11/2026
Attorney Name: ELLEN RELKIN
Firm Name: WEITZ & LUXENBERG PC
Address: 700 BROADWAY
NEW YORK NY 10003
Phone: 2125585500
Name of Party: PLAINTIFF : William Douglas
Name of Defendant's Primary Insurance Company (if known): Unknown

Case Type: PRODUCT LIABILITY
Document Type: Complaint with Jury Demand
Jury Demand: YES - 6 JURORS
Is this a professional malpractice case? NO
Related cases pending: YES
If yes, list docket numbers: ATL-L-000618-26
Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO
Does this case involve claims related to COVID-19? NO

Are sexual abuse claims alleged by: William Douglas? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO
If yes, please identify the requested accommodation:

Will an interpreter be needed? NO
If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO **Consumer Fraud?** YES **Medical Debt Claim?** NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

06/11/2026
Dated

/s/ ELLEN RELKIN
Signed

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Williams Douglas

(b) County of Residence of First Listed Plaintiff Shelby County, TN
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Ellen Relkin, Esq., Laura J. Baughman, Esq. (PHV app forthcoming) Weitz & Luxenberg, 220 Lake Drive East, Suite 210, Cherry Hill, NJ 08002, (856) 755.1115

DEFENDANTS

Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc.

County of Residence of First Listed Defendant Somerset County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Brian M. Lands, Esq., Shook, Hardy & Bacon L.L.P., Two Commerce Square, 2001 Market Street, Suite 3000, Philadelphia, PA 19103 (215) 278.2555, *(Attorney for Regeneron Pharmaceuticals, Inc.)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☐ 1 Original Proceeding
- ☒ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. §§ 1332, 1441, and 1446

Brief description of cause:
Personal injury action arising from use of prescription medication

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ Greater than $75,000

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 6/11/2026

SIGNATURE OF ATTORNEY OF RECORD */s/ Brian M. Lands*

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____